The Pharmaceutical Manufacturer's Duty to Warn: A Comparative Study between German and Canadian Pharmaceutical Products Liability Laws

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Preface:

This thesis presents a comparative analysis of the pharmaceutical manufacturer's duty to instruct the public about inherent product risks, based on German and Canadian liability laws. It shows the development of the case law, as well as the legal and procedural difficulties involved in litigation in both legal systems, by identifying which information the pharmaceutical manufacturer must disclose and showing how to present this to the medical profession and in particular to the consumer, in order to meet requirements and expectations imposed by law, in order to enhance public health and to avoid liability claims.

I would like to express my sincere appreciation to my Supervisor, Professor John Irvine, for his generous time, invaluable expertise and extraordinary assistance, and to Professor Dr. DeLloyd J. Guth, Director of the Master of Laws program for his continuous encouragement and moral support throughout the course of the program. I also thank, Professor Philip H. Osborne as the Second Reader, and especially the External Reviewer Tony Weir, Faculty of Law, University of Cambridge, England. for his sophisticated suggestions, comments and productive criticisms. My thanks as well to Professor Hans Prütting, Cologne, Germany, for his valuable legal advice.

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Frequently used Abbreviations:

AMG	Arzneimittelgesetz (Pharmaceutical Products Act)
BB	Betriebs - Berater
BGB	Bürgerliches Gesetzbuch (German Civil Code)
BGH	Bundesgerichtshof (Federal Supreme Court)
BGHZ	Entscheidungen des Bundesgerichtshofes in Zivilsachen (Decisions of the Federal Supreme Court in civil matters)
DAZ	Deutsche Apotheker Zeitung
DB	Der Betrieb
JZ	Juristenzeitung
JuS	Juristische Schulung
NJW	Neue Juristische Wochenschrift
NJW-RR	Neue Juristische Wochenschrift - Rechtsprechungsreport
Pharm.Ind.	Pharmazeutische Industrie
ProdHaftG	Produkthaftungsgesetz (Product Liability Act)
RG	Reichsgericht (German Supreme Court)
RGZ	Entscheidungen des Reichsgerichts in Zivilsachen (Decisions of the German Supreme Court in civil matters)
VersR	Versicherungsrecht
WM	Wertpapier-Mitteilungen

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Part 1: German Law

A. Pharmaceutical Product Liability for the breach of Instruction- and Warning duties

I. The Liability System for pharmaceutical Products

The law of product liability in Germany is, roughly speaking, divided into two major categories: the liability based on fault (*verschuldensabhängige Haftung*) and liability independent of fault (*verschuldensunabhängige Haftung*). Fault liability is regulated by the German delict or tort law (*Deliktsrecht*[1]), §§ 823 ff. of the German Civil Code (*Bürgerliches Gesetzbuch - BGB*), and embraces liability for intentional conduct (*vorsätzliches Verhalten*) or negligence (*Fahrlässigkeit*).

The law governing liability independent of fault in the field of pharmaceutical product liability law manifests itself through the product related risk[2] or absolute[3] liability

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[1] In German law the terms *Delikt* and *unerlaubte Handlung* (unlawful conduct) are used synonymously. They may be translated by the English term "tort" or the Scottish term "delict", keeping in mind that tort liability in the traditional meaning of the common law embraces more remedies: Klaus Vieweg, *Introduction to German Law*, ed. by Werner F. Ebke & Matthew W. Finkin (London: Kluwer Law International,1996) at 197: hereafter cited as Vieweg in: Ebke/ Finkin.

[22] The distinction between strict and risk liability is adopted on purpose, because German liability law, as far as it is independent of fault, is regulated in special laws, which presents different types of no-fault liability laws.

By way of clarification:

- *Verschuldensunabhängige Haftung* (liability independent of fault) **(= strict liability)**, *e.g.*, ProdukthaftG, ensues from the objectively unlawful conduct of the tortfeasor, *i.e.*, according to the regulations of the ProdukthaftG liability is imposed only for objectively foreseeable, recognizable and avoidable product defects (objective breach of a duty of care) - therefore no liability in the case of development defects.
- Gefährdungshaftung **(= risk liability)**, which also belongs to the category of *verschuldensunabhängiger Haftung* relates to a *Gefährdungstatbestand* (a dangerous factual circumstance) independently of any *Sorgfaltspflichtverstoß* (breach of the duty of care).This means that according to traditional understanding liability is imposed even for injuries and damage caused by mere accident and chance, which typically occur in connection with the creation or operation of particular sources of peril, such as the operation of dangerous machines, motor vehicles or trains and also by producing pharmaceutical products which create chemical reactions. Therefore under this category development defects are

(*produktbezogene Gefährdungshaftung*) provided by §§ 84 ff. of the Pharmaceutical Products Liability Act (*Arzneimittelgesetz - AMG*). The subject of this paper comprises both the manufacturer's delictual or tortious liability for negligence (*deliktsrechtliche Fahrlässigkeitshaftung*) and the product related risk liability for damages caused by pharmaceutical products. Both liability concepts compete equally and cumulatively with each other; in other words, they present concurrent or conflicting bases of claim (*Anspruchskonkurrenz*). This means that they are triggered by different conditions, have different legal liability consequences and have to be judged independently according to their essential content (*Inhalt*) and the procedures they involve (*Durchsetzung*).[4] Within the realm of fault-independent liability law a third source of product liability regulations is provided by the Product Liability Act (*Produkthaftungsgesetz - ProdhaftG*), which lays down strict liability rules for defective products. This strict liability according to the Product Liability Act stands besides and is supplemented by the fault based delict product liability law following out of §§ 823 ff. *BGB*.[5] However, the Product Liability Act does not apply to cases of liability for pharmaceutical products falling under the liability regulation of § 84 *AMG*[6]. This is because § 84 *AMG* is a special regulation ranking in

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included. Roughly speaking *Gefährdungshaftung* is a special construct within the whole concept of *verschuldensunabhängiger Haftung*, referring partially to other conditions and liability consequences.

[3] This term could be considered as the generic term for both, risk and strict liability.

[4] Hans Josef Kullmann, *"Haftung des pharmazeutischen Unternehmers für nicht wirksame Arzneimittel"* [1983] Pharma Recht 196 at 196.

[5] § 15 II *ProdhaftG*; Kullmann in: Hans Josef Kullmann & Bernhard Pfister, *Produzentenhaftung* (Berlin: Erich Schmidt Verlag, 42. Lieferung April/1998) Kza. 3612 1 at 4a: herafter cited as Kullmann in: Kullmann/ Pfister.

[6] § 15 I *ProdhaftG*, which essentially corresponds to § 84 *AMG* in wording:

> If, as a result of the administration of a pharmaceutical product intended for human use which was distributed to the consumer within the purview of this law and which is subject to compulsory marketing authorization or is exempted by ordinance from compulsory marketing authorization, somebody is killed, his body or his health injured, the regulations of the Product Liability Act must not be applied.

priority to - in the sense of excluding - the Product Liability Act. Therefore the Product Liability Act does not fall within the direct scope of this paper but will come into consideration when the discussion turns to liability for those products, such as breast implants, which, according to Canadian law, are pharmaceutical products but in German law fall outside the regulations of its Pharmaceutical Products Act, because they are not drugs within the scope of § 2 *AMG*[7].[8] To summarize, then, pharmaceutical product liability may arise as tort liability under § 823 I, II[9] *BGB*, as well as risk liability imposed by the Pharmaceutical Products Act.

II. Product liability based on tortious negligence liability

1. Liability under 823 I *BGB*

Liability for defective or hazardous products, the so-called manufacturer's product liability (*Produzentenhaftung*) or product liability (*Produkthaftung*) was developed out of the tortious negligence liability (*deliktsrechtlichen Fahrlässigkeitshaftung*) according to § 823 I *BGB*.

§ 823 I *BGB* provides:

> A person who, intentionally or negligently, and unlawfully injures the life, body, health, liberty, property or any other right of another person is bound to compensate him for any damage arising therefrom.[10]

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[7] § 2 *AMG* provides the definition of drugs under the Pharmaceutical Products Act.

[8] Since the enforcement of the *Medizinproduktegesetz*, human implants are no longer considered to be drugs in the scope of § 2 *AMG*. The Product Liability Act provides liability for those products only, which are not included in the liability regulations of the Pharmaceutical Product Law, such as animal drugs and homeopathic drugs, Walter Rolland, "*Zur Sonderstellung des Arzneimittelherstellers im System des Produkthaftungsrechts*" in: *Festschrift für Werner Lorenz*, ed. by Bernhard Pfister & Michael R. Will (Tübingen: J.C.B. Mohr-Paul Siebeck, 1991) 193 at 199: hereafter cited as *Festschrift für Lorenz*. The same is true about so-called *Defekturarzneimittel*, which are pharmaceutical products, that are mass-produced in advanced by the pharmacist. Furthermore the Product Liability Act applies to cases, where pharmaceutical products, by way of an exception, cause damage to *things*; Kullmann in: Kullmann/ Pfister, Kza. 3612 at 2.

[9] Roman numbers after codes, *e.g.*, § 823 I, II *BGB*, in German law writing stands for their subsections, such as here subsection 1 and 2.

[10] For an English translation of the German Civil Code see Simon L. Goren, "*The German Civil Code*" (Littleton, Colorado: Rothman & Co.,1994) at 3 ff.

For an action to be based on § 823 I *BGB*, certain requirements have to be met. There must be an interference with one of the enumerated rights or interests or any "other right", the so-called absolute rights. Since a tort claim supposes the defendant's responsibility, either an action or a nonfeasance is necessary. Furthermore a causal connection between the tortfeasor's action or nonfeasance and the violation of the right or interest is required. The absolute right must have been injured unlawfully and culpably. Lastly, a compensable detriment (*ersetzbarer Schaden*) and a causal connection between the interference with the absolute right and the damage suffered, are required, as well as details concerning the type, content, and extent of the compensable detriment. The plaintiff's claim has to show and prove all these elements.

Tort remedies consist of restitution in kind (*Naturalherstellung*) and compensation for material damages (*Schadensersatz*), as well as compensation for non-material damages (*Schmerzensgeld*). In this lies the essential importance of the fault based negligence liability as opposed to the no-fault liability regulations, *e.g.*, those under the Pharmaceutical Products Act, which in general do not provide compensation for non-material damages. This explains also why a lot of product liability cases have been decided on the ground of fault liability according to § 823 *BGB*, even though the elements of a special code providing for risk or strict liability would also have been met.

However, typically in product liability cases it is - so to say - not the direct conduct of the tortfeasor against another person's interest under § 823 I *BGB* that is the center of gravity concerning the action the manufacturer is accused of; it is rather the consequence of distributing a defective manufactured product that has to be seen as the violation of the

injured party's "absolute right", as mentioned above. It is a condition for claiming damages based on § 823 I *BGB* in product liability cases (*i.e.*, that a manufacturer in connection with producing or distributing products will be liable to an injured person under delict law) that the violation can be shown of a so-called legal obligation to maintain safety (*"Verkehrssicherungspflicht"*) incumbent on him.[11] This means that in product liability cases the action or nonfeasance of the manufacturer requires special consideration in its application to violations of the *"Verkehrssicherungspflicht"*. The term *"Verkehrssicherungspflicht"* is not easy to translate; but its meaning can be summarized by saying that whoever, by his activity or through his property, establishes in everyday life a source of potential danger which is likely to affect the interests and rights of others, is obliged to ensure their protection against the risks thus created by him.[12] The general legal obligation to maintain safety, which could be considered as a fairly accurate translation for the term *"Verkehrssicherungspflicht"* (out of consideration for others), is based on the idea that anyone who creates sources of peril is obliged to take precautions for the protection of third parties.[13] This is based on the idea that creating an antecedently dangerous or potentially dangerous activity or state of affairs should give rise to a duty of care, which translates the term *"Sorgfaltspflicht"*. To explain this in other words: everybody has the legal duty of care (*"Sorgfaltspflicht"*) to avoid, avert or not to create dangers for other's interests presented by his conduct. This is called the legal duty to

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[11] 51 *Entscheidungen des Bundesgerichtshof in Zivilsachen* (decisions of the Federal Supreme Court in civil matters) 91 at 105 -"*Hühnerpest*" ("fowl-pest"): herafter cited as *BGHZ*.

[12] B. S. Markesinis, *A Comparative Introduction To The German Law of Torts*, 2nd ed. (Oxford: Clarendon Press, 1990) at 64.

[13] Heinz Thomas in: Otto Palandt, *Bürgerliches Gesetzbuch*, 51st ed.(München: C.H. Beck'sche Verlagsbuchhandlung) § 823 para. 58 at 919: herafter cited as Thomas in: Palandt, *BGB*.

maintain safety (*"Verkehrssicherungspflicht"*[14]).[15] In this sense, *"Verkehrssicherungspflichten"* are to some extent comparable with the "duty of care" in the Canadian law of negligence. In the context of tortious negligence liability the courts have developed these *"Verkehrssichungspflichten"* to define more specifically the reproachable conduct - whether an action or omission, both are open to consideration[16] - which the tortfeasor is accused of and which makes a person liable according to § 823 I *BGB*.

This means in the area of product liability, that the product manufacturer who produces and sells goods and thereby enters into an activity that is generally capable of causing danger to the public, *e.g.*, if the product is defective - has a general legal duty not to bring onto the market products which carry avoidable risk of danger or of causing damage. The manufacturer who produces unsafe or defective products and brings them onto the market, violates his *"Verkehrssicherungspflicht"* and is liable towards everybody who suffers damage or injury in health or property. Therefore one major focus of product liability cases is the product defect, which in pharmaceutical product liability means the

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[14] Or *"Verkehrspflicht"*, which is a mere or comprehensive expression connoting a duty owed to the person or to persons generally.

[15] Irene Fahrenhorst, *"Instruktionspflicht des Herstellers eines Kintertees - BGHZ 116, 60"* [1994] Juristische Schulung 288 at 289: hereafter cited as JuS.

[16] *E.g.*, concerning the manufacturer's duty to instruct or duty to warn the action could be illustrated by the distribution of a product with false instructions and the omission could be discerned in an insufficient instruction given to the consumer, Fahrenhorst, [1994] JuS at 289. For further details on the distinction between the breach of a *"Verkehrssicherungspflicht"* by conduct or omission and the starting position that both is possible, also Kullmann in: Kullmann/ Pfister, Kza. 1515 at 4 f.; Erwin Deutsch *"Entwicklungstendenzen des Schadensrechts in Rechtsprechung und Wissenschaft"* [1967] Juristische Schulung 152 at 157.

realization of a drug's inherent danger.[17] The pharmaceutical product risk typically realizes itself by excess, side-effect, interaction or inefficacy or ineffectiveness.[18]

Courts and scholars have identified a number of duties in regard to possible product defects, that are usually subdivided into different categories concerning design, manufacturing, instruction, monitoring, and recall.

2. The manufacturer's duties of care imposed by case law, the categories of product liability or defect types

Depending on the different stages, from developing, manufacturing and marketing of a product, the defect may be of a different type. The individual product defect is classically defined and distinguished by the following categories:

a. Defects in design (*Konstruktionsfehler*)

Definition: a defect in design exists, when a product through its construction[19] or technique conception[20] gets a characteristic or quality which makes it, in regard to its

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[17] Erwin Deutsch, *Medizinrecht*, 3rd ed. (Berlin: Springer, 1997) at 603 para. 909.

[18] While the first three alternatives are already contained under the liability imposed by § 84 *AMG*, the zero-effect of a drug does not fall under this provision, even though the *AMG* regulations in general (*inter alia*) aim for efficacy or effectiveness of drugs, so that concerning this the delict law product liability regulations have to be resorted to. This issue will be described in detail below.

[19] This refers, *e.g.*, in the case of pharmaceuticals, cosmetics, beverages, processed food, etc., to the responsibility for the development of a safe recipe, which comes prior to the manufacturing process; for further detailed explanation, Kullmann in: Kullmann/ Pfister, Kza. 1520 at 7 ff.; in the context of pharmaceutical products the term "recipe-defect" was suggested rather than "design-defect" by Ernst von Caemmerer, "contribution to speech from Erwin Deutsch "*Die klinische Forschung am Menschen im amerikanischen und internationalen Recht*" [1987] Karlsruher Forum 11 ff." [1987] Karlsruher Forum 21 at 21.

[20] This refers to the development of technical products, which ought to be constructed according to the present state of technologically possible safety, including most recent scientific knowledge and empirical experience; *BGH* [1952] Versicherungsrecht 357 at 358 - *"Rungenverschluß"* ("stake/ stanchion lock"): herafter cited as VersR; *BGH* [1956] VersR 625 at 626 - *"Karussell"* ("merry go round"); *BGH* [1960]

promised or intended use, deficient or unsafe for ordinary use (*bestimmungsgemäßer Gebrauch*), *e.g.*, sharp-edged or poisonous toys[21], an easily inflammable evening dress or wig, or a motor-vehicle without brakes[22].

Typically product defects in design are due to a defect at the conception stage of the product. Therefore design defects normally affect the entire production series, because the product, due to its conception prior to its manufacturing process, falls short of a reasonable technical standard or scientific knowledge available that could have been expected according to the state of the art.[23] This includes background research as well as the product's planning.

Regarding pharmaceutical products this means that the drug during "development"[24] receives a "construction" that does not meet the required duty of care regarding efficacy, effectiveness, side-effects and interaction with other products. The defect can be due to a deficient examination of the drug or to non or insufficient consideration of available

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VersR 1095 at 1096 - *"Kühlanlage"* ("refrigerating-plant"). For further detailed explanation see Kullmann in: Kullmann/ Pfister, Kza. 1520 at 10 ff.

[21] Kullmann in: Kullmann/ Pfister, Kza. 1520 at 16 f.

[22] Christoph Landscheidt, *Das neue Produkthaftungsrecht*, 2nd ed. (Berlin: Verlag neue Wirtschafts-Briefe, 1992) at 48 f.

[23] Kullmann in: Kullmann/ Pfister, Kza. 1520 at 8 ff.; Fahrenhorst, [1994] JuS at 289; for English explanations see, S. M. Waddams, *Products Liability*, 3rd ed. (Scarborough: Carswell, 1993) at 39, with further examples in footnote 143.

[24] For the sake of clarification: in pharmaceutical product liability the term "development defect" is used whereas in this context in general product liability the more technical term "*Kontruktionsfehler*" (design defect) is used, whereas the so-called development defect by definition describes defects that were unavoidable - *i.e.*, not due to someone's fault - and therefore does not impose liability on the manufacturer (which will be explained hereafter).

literature; *e.g.*, contrast-products which provoke severe late consequences[25] or a toxicity caused by the interaction of an active agent with the solvating agent[26].

Nevertheless, design defects have to be distinguished from so-called development defects (*Entwicklungsfehler*). These are, by definition, subsequently discovered defects that were unknown when the product, meeting the standard prevailing at the-time, was first put on the market; *e.g.*, a pesticide developed to protect apple trees from apple scab. Over the years the pesticide ceased to be effective against a particular fungus which had developed a resistance against the product and made it useless: such a development nobody could have predicted, with the scientific knowledge available at the time the product was first put on the market.[27]

Such development defects are not ordinarily considered to be attributable to the manufacturer. Therefore he is not liable for development defects under the provision of § 823 I *BGB*, because he was not at fault. In contrast to that, as we shall see, a pharmaceutical manufacturer cannot in this way entirely escape liability for development defects in pharmaceutical products. According to the special provisions in the Pharmaceutical Products Act (§ 84 *AMG*), which provide for risk liability, he also has to carry the risk of unforeseeable subsequently discovered development defects.

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[25] 20 *BGHZ* 61 at 62 - "*Thorotrast*", a radioactive contrast-product, which had been used for arteriography of the patient's leg artery and caused liver cirrhosis; *BGH* [1961] VersR at 810; *KG* [1975] VersR 75 at 427.

[26] See reference by Deutsch, at 604 para. 910, footnote 75: mixture of Sulfanilamid with Diäthylenglykol, which caused 105 deaths in 1939.

[27] 80 *BGHZ* 186 at 190 - "*Apfelschorf I 'Derosal'*" ("apple scab I").

b. Defects in manufacture (*Fabrikationsfehler*)

Definition: in these cases the planning and method of construction in itself is perfectly sound, but during production occasionally individual products occur which deviate randomly from the intended standard - usually in production line manufacture - and these are called manufacturing defects.[28]

Here the manufacturer did not intend to produce the product as it left his hands, but for some reason, usually the negligence of an employee or an inadequate system of production or inspection, the manufacturer's intention was not carried out.[29]

Typically the product contains something which ought not to be there, or something is absent that was supposed to be present, which then leads to an unsafe or even dangerous usage; *e.g.*, a mouse in a Coca-Cola bottle.

Accordingly, a defect in manufacture in the context of pharmaceutical products typically refers to pureness, cleanness, composition or risk of contamination; *e.g.*, the wrong mixture of a pharmaceutical product, use of chemically impure substances, (*e.g.*, because the machines were not properly cleaned) or a vaccination that carries active viruses after being bottled into bacterially impure containers[30].

The breach of the duty of care in this case, just as in that of design defects, lies mainly within the scope of the manufacturer's organization and control. However, the manufacturer may escape liability for defects classified as so-called "runaways"

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[28] 104 *BGHZ* 323 at 323 ff. - *"Limonadenflasche"* ("soft-drink bottle"); Landscheidt, at 49; Kullmann in: Kullmann/ Pfister, Kza. 1520 at 28 ff.

[29] Fahrenhorst, [1994] JuS at 289; for an English explanation see, Waddams, at 38.

("*Ausreißer*"), which are unavoidable defects in manufacture that accidentally occur, even though the manufacturer himself has met the expected duty of care.[31]

c. Instruction defects (*Instruktionsfehler*)

Definition: the defect in this case is a lack of instructions or the giving of insufficient warning, depending on the kind of danger inherent in the product's use.[32]

The product itself is not defective after it leaves the manufacturer's business, but the properly manufactured and non-defective product can cause harm when it is not properly used as ordinarily intended; *e.g.*, weapons or hydrochloric acid. The danger lies in its very nature and is unavoidable. But damages can be avoided, or the risk of damages can be reduced, if the product is appropriately and carefully used. In this regard the manufacturer has an obligation to avert the danger and owes a duty to try to ensure that the product is only used in a safe way, a duty discharged by giving an adequate warning about inherent dangers, with sufficient instruction for the harmless use of the product.[33] Whether and to what extent the manufacturer has a duty to warn or instruct in the actual case depends on the extent to which the average user can be expected to use the product without risk; or if the manufacturer, due to the special features of the product and in view of the pre-

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[30] 51 *BGHZ* 91 at 91 ff. - "fowl-pest".
[31] Thomas in: Palandt, *BGB* § 823 para. 205 at 943; Kullmann in: Kullmann/ Pfister, Kza. 1520 at 28; Fahrenhorst, [1994] JuS at 290.
[32] Landscheidt, at 50; Kullmann in: Kullmann/ Pfister, Kza. 1520 at 33 ff.
[33] *BGH* [1960] VersR 342 at 243 - "*Klebemittel*" ("glue adhensive"); NJW 1987, 372, 373 = VersR 1987, 102 at 103 - "*Verzinkungsspray*"; Fahrenhorst, [1994] JuS at 290 referring to *BGH* NJW 1992, 560 at 560 ff.; Walter Rolland "*Produkthaftungsrecht*" (Köln: Bundesanzeiger, 1990) para 32 at 332.

assumed knowledge of an average user, has to expect that specific concrete dangers might occur.[34]

In this connection the manufacturer has to take into account that, in relation to certain products, the required knowledge and skill for their safe use cannot generally be presupposed. Accordingly he also has to consider that the product will not always be properly used. His obligation to avert danger is also extended to dangers arising from improper uses which are reasonably foreseeable and not far-fetched or remote. The manufacturer also has to consider other user modes, as far as these are not beyond normal pre-vision, because he cannot rely on the assumption that his product will be used exclusively by experts for professional use. There is a limit, however, when it comes to an intentional "ab-"use by clear misuse not in accordance with the contemplated user purpose.[35]

In this context a distinction is commonly made between the duty to give adequate user instructions, and the duty to warn about inherent hazards of the product.

aa. Instruction for appropriate and ordinary use, compliant with the intended use of a product (*Anwendungswarnung*).

User instructions regarding the appropriate and ordinary use of a product, compliant with the intended usage (*Anwendungswarnung*) are, for example, necessary for complex or complicated or extraordinary work tools and machinery.

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[34] *BGH* [1966] VersR 542 at 543 - *"Fachleute"* ("experts"); *BGH* [1975] Betriebs-Berater 1031 at1032: hereafter cited as BB = *BGH* Neue Juristische Wochenschrift [1975] 1827 at 1829 - *"Spannkupplung"*:

This is the case, *e.g.*, where an apparatus is intended to be used in combination with others or with other supplies. Then the manufacturer has to give *inter alia* the necessary instruction about the possible results of combinations with other equipment.[36]

However, in general, everybody has to consider for himself how best to use a product, if its handling does not seem to require expert knowledge. Where simple tools of daily usage are involved - such as scissors, light bulbs, kitchen knives - the manufacturer is not obligated to give instructions for adequate usage. Any knowledge that can be assumed on grounds of general life experience does not need to be made subject to a user instruction or explanation.[37]

bb. Adequate information[38] about those risks inherent in the product's use, of which the manufacturer is aware.

A typical example for adequate information about inherent risks of a product would be the side-effects of pharmaceutical products.

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hereafter cited as NJW; 99 *BGHZ* 167 at 178 - *"Honda"*; *BGH* [1986] NJW 1863 at 1864 - "Überrollerbügel" ("roll-bar"); 116 *BGHZ* 61 at 67 = *BGH* [1992] NJW 560 at 561.

[35] Rolland, at 333 para 32.

[36] 99 *BGHZ* 167 at 172 - *"Honda"*.

[37] *BGH* [1975] BB 1031 at1032 = *BHG* [1975] NJW 1827 at 1829 - *"Spannkupplung"*; Rolland, at 333 para. 32.

[38] The difference between information and instructions or warnings is: *e.g.*, in the case of pharmaceutical products "information" is the generic term for side-effects, interaction, etc., whereas "instructions" are directions given to explain the safe use of the product.

cc. Sufficiently explicit warning of consequences (*Folgenwarnung*).

A warning comes into question when dangerous consequences may be anticipated as arising from the product's intended use, *e.g.*, inflammable glue.[39]

A warning has also to be considered, if a product only threatens certain people and suggests dangerous consequences as a result, *e.g.*, warnings to store or keep this product out of children's reach.

Other possible consequential warnings relate to the effects of other forms of reasonably foreseeable (mis-) use, excluding intentional abuse; *e.g.*, a warning about the risk of explosion presented by the mixture of two violently incompatible drain-cleaning compounds.[40]

However the duty to warn ends in cases where obvious dangers are necessarily incidental to improper use of product.

Finally it needs to be kept in mind that an existing defect in design or manufacture cannot be wiped away by giving the consumer notice of it, because the instruction duty is not a device for decreasing the required security standard.[41] This means the manufacturer

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[39] As in *Lambert v. Lastoplex Chemicals Co. Ltd.* [1972] S.C.R. 569, 25 D.L.R. (3rd) 121.
[40] As in *Smithson et al. v. Saskem Chemicals LTD. et al.* (1985) 34 C.C.L.T. 195; [1986] 1 W.W.R. 145, 43 Sask. R. 1 (Q.B.)
[41] Rolland, at 334 para. 33.

cannot escape liability for omitting reasonably expectable, danger-averting measures simply by giving a warning.[42]

d. Development defects (*Entwicklungsfehler*):

Definition: typically, in these cases the product will have been manufactured in accordance with the technological knowledge and standard of science of its time and will also have been of an adequate standard when it was put on the market; but subsequently acquired information reveals its potentially harmful effects.[43] For example, a pharmaceutical product may fail certain persons, meaning either that it "doesn't work" in the sense of being ineffective, or it does actual harm. Its dangerousness might be realized only through changes brought about by the influence of external circumstances, environmental circumstances for instance.[44]

The category of development defects describes defects that are neither foreseeable nor avoidable at the time of manufacture or distribution, because the manufacturer was not able to produce a better product given the state of the art at that time. While in the beginning of product distribution the product defect or pharmaceutical product risk was either non-existent or not recognizable, it now becomes reality. The decisive difference from those categories mentioned above lies in the circumstance that the product later becomes classifiable as defective, because subsequent developments in the state of the art now show the product to be defective. In other words the product is subsequently

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[42] Kullmann in: Kullmann/ Pfister, Kza. 1520 at 34.
[43] Markesinis, at 81.

considered to be defective as a result of additional technological and scientific knowledge that did not exist before; *e.g.*, emerging awareness that certain substances in plastic toys are toxic, or tooth decay caused by sweetened herbal tea for children - "Baby-Bottle-Syndrome"[45]. Examples for pharmaceutical products would be the discovery that thalidomide used by pregnant women caused malformation in their babies[46], or that breast implants rupture after a certain time[47].

The question is, whether the manufacturer is liable for the first case that discloses the development defect of his product. In other words, does he have to carry this **development risk**, or can he use the defect in development as a defense?

In general, German product liability law does not impose liability on manufacturers for damages that are due to dangers that were not known or recognizable according to the standard of science and technique at the time of distribution,[48] because case law on this matter agrees that the manufacturer is not at fault under the provision of § 823 *BGB*. Following this principle, German product liability law has excluded development defects from the categories of possible defect that make a manufacturer strictly liable for damages caused by his products under the Product Liability Act. [49] The reason for this has been the belief that making manufacturers carry such a risk could hinder technological progress. To make them strictly liable for such risks would also run counter to the rationale for

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[44] Deutsch, at 604 para. 913.
[45] 116 *BGHZ* 61 ff. - "*Kindertee* I" ("children's tea I").
[46] *LG* Aachen [1971] Juristenzeitung 507 at 507 ff. - "*Contergan*" ("Thalidomide"): hereafter cited as *JZ*; Landscheidt, at 51.
[47] *Hollis v. Dow Corning Corp.* [1995] 27 C.C.L.T. (2d) 1 at 19.
[48] Hans Josef Kullmann, *Produkthaftungsgesetz*, 2nd ed. (Berlin: Erich Schmidt Verlag, 1997) at 54-57.
[49] § 1 II Nr. 5 *ProdhaftG*; Kullmann, at 54; Landscheidt, at 50 f.

imposing such a strict liability in the first place, because one of the justifications for imposing strict liability on the manufacturer is his ability to detect and avoid the defect.[50] Therefore the manufacturer as a general rule does not carry these so-called development risks and generally does not have to compensate for damages caused by a development defect, as they simply do not expose him to liability in a lawsuit. Therefore classification of a defect as development defect serves as a defense for the manufacturer in a lawsuit.[51]

The law of pharmaceutical products is the leading exception in this respect, as the "development defect" argument is not available to the defense. This is because under the Pharmaceutical Products Act (*AMG*), which imposes risk liability for pharmaceutical products, the manufacturer is liable irrespective of whether damage caused by his product is the result of defective design, manufacture, labelling or even development defects.[52] The inclusion of development defects into the liability categories, which means that the manufacturer has to carry the risk of later discovery of such defects, is what makes the risk liability for pharmaceutical products so exceptional. With this, the most important area of development risk occurrence is regulated by special law, because outside of this

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[50] Markesinis, at 81.

[51] The defense hereby admitted resembles the "state of the art" -defense recognized in American law, but it cannot be qualified as exactly the same, because it does not exclude all kinds of development defects, only those potential risks and dangers that could not from an objective point of view possibly been recognized by anybody. Whereas if the dangers were known, but could not be eliminated or controlled by a better design or construction due to the scientific and technical standard during the time of manufacturing - so-called "developmental gaps", the legal exclusion from liability does not apply; Kullmann, at 54; for further details, such as the terms "scientific and technical standard", the distinction between the objective possibility of recognizing the development defect, and the subjective blame imputed to the manufacturer at fault, referring only to the provisions of § 823 *BGB*, also see at 55-57.

[52] § 84 *AMG*; Kullmann, at 159; Landscheidt, at 51; for an English explanation see Markesinis, at 81.

area of chemical and pharmaceutical products the relevance of development defects is seen as rather minor.[53]

Concerning other product liability cases, however, (meaning, other than pharmaceuticals) the retention of the state of art defense in the German product liability law only helps the manufacturer to escape liability, when he can contend that he could not have known or done better, because the relevant scientific or technical knowledge now revealed was not available at the time of product distribution. After the first incident, though, if the manufacturer can reasonably be expected actually to become aware of such recently revealed knowledge, he cannot be exculpated any longer, if he fails to respond appropriately.[54] Also the "development risk" defense does not absolve a manufacturer from continuously observing his product to become aware of such development defects. This obligation also includes and creates multiple additional duties.[55]

After the manufacturer becomes aware (or ought to become aware) of the development defect or the potential harmful consequences of his product, he is required as a matter of legal obligation to fulfill further safety precautions (precautionary measures), namely to warn consumers or even withdraw the product from the market.

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[53] Landscheidt, at 51.
[54] Kullmann, at 55 f.
[55] *E.g.*, duty to warn or recall the product, see following chapters f. and g.; Markesinis, at 81.

However, development defects have to be distinguished from subsequent improvements, that have been made at a later time.[56] In this case the product cannot be considered as defective if it is merely not up-to-date. An example would be safety technology that falls short compared with newer products; *e.g.*, a safety device that could be installed on existing products, such as seat belts.[57]

e. Monitoring duty (*Produktbeobachtungspflicht*):

Definition: the Monitoring duty means the obligation continuously to observe and control the product after it has been put on the market in light of the new standard and changes in science and the technological knowledge of the time, so as to discover hitherto unknown development defects which will then generate various other obligations; *e.g.*, observation and monitoring of the effectiveness of a pesticide used to protect apple trees from apple scab.[58]

The existence of so-called post-marketing duties is based on the idea that the manufacturer's duties do not end after the product is on the market.[59] The monitoring duty includes the permanent quality control of distributed products and also a duty to keep an eye on various other products that are likely to cause dangers in combination with one's own product[60]; *e.g.*, dangerous mixtures of housecleaning products. This kind of

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[56] Landscheidt, at 51, also for an English explanation Waddams, at 44-46.
[57] Example used by Landscheidt, at 51.
[58] 80 *BGHZ* 199 at 202 ff. - "*Apfelschorf II 'Benomyl'*" ("apple scab II").
[59] Deutsch qualifies this duty as a sub-category of the *Verkehrspflicht* (general duty owed to the public).
[60] 99 *BGHZ* 167 at 172 - "*Honda*".

obligation is well known in pharmaceutical product law as the duty to observe the pharmaceutical product with regard to its main and side-effects, its interaction with other drugs or the like for evidence of contra indications. If side-effects are reported other than those that were expected, the package insert and expert information ought to warn about it.[61] This subsequent duty to warn applies to newly realized contra-indications as well as to hazardous interactions.[62]

It follows from the foregoing that the manufacturer does not have to carry the development risk until it becomes aware or ought to become aware of a defect, *i.e.*, in non-pharmaceutical cases, this means also that the post-marketing duty is limited to an ongoing monitoring duty.

In German law the Federal Supreme Court has even extended the manufacturer's post-marketing duties concerning its own product to the performance of component parts, by finding a manufacturer of motorcycles liable for not warning the consumer about the risk of destabilization when applying to the motorcycle some extra equipment produced by another manufacturer.[63]

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[61] If the danger exists, that the pharmaceutical product will be clandestinely tampered with, a duty might even be imposed to pack the product in a way that a dangerous dealing with it will be impossible or at least will be recognizable as such, Deutsch, at 605 para. 914 referring to Ilsroth v. Johnson & Johnson 700 F.Supp. 151 (1989).

[62] Deutsch, at 605 para. 914. This is because the pharmaceutical entrepreneur who distributes pharmaceutical products is legally obligated (§ 11 I Nr. 7 and § 11 a I Nr. 7 *AMG*, also under § 823 I, II *BGB*) to give the corresponding information in package inserts and expert information.

[63] 99 *BGHZ* 167 at 172 - "*Honda*".

As some instructional defects only become recognizable after distribution of the product and possible misapplication by the consumer, a product monitoring duty can also arise in so far as dangers are concerned which result from newly perceived inadequacies in recommended user applications or other instructions given.[64]

f. Reactive duty to warn[65]:

As a corollary to his monitoring duty the manufacturer has - as already considered above - a duty to warn the consumer about the subsequently discovered defects or inherent risks of his product or the potential harmful consequences that can be caused by using it in combination with other products. Under certain circumstances he may be even obliged to instruct the public (in the TV news or press) not to use his product any more.[66]

g. Duty to recall (*Rückrufpflichten*):

Where the duty to warn the consumer or the public, about certain dangers in connection with the product would be considered inadequate or unreasonable as a means of preventing the expected damage likely to be caused by the product, the manufacturer's duty can become a duty to recall or withdraw the product from the market.

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[64] Kullmann in: Kullmann/ Pfister, Kza. 1520 at 43.
[65] Dieter Hart: in Hart et al., *Das Recht des Arzneimittelmarktes* (Baden-Baden: Nomos Verlagsgesellschaft, 1988) at 151, 154, who distinguishes between the instruction and warning duty before and with distribution of the product and those arising after, out of monitoring and observing the product.
[66] Kullmann in: Kullmann/ Pfister, Kza. 1520 at 49; for an English explanation, see Waddams, at 45.

Again, we must distinguish the situation that arises out of subsequent developments in the state of the art from that where a subsequent improvement concerning the product is discovered, such as a safety device that could be installed on existing products.[67] For instance, the installation of seat belts in cars has become a general practice to meet requirements in safety standards at the present time. This raises the question, whether subsequent improvements impose on the manufacturer a positive duty to act.[68] That will probably depend on the quality of the danger that could possibly be reduced in relation to the effort that can reasonably be expected from the manufacturer. Here we obviously have to make distinctions in terms of improvements between additional safety devices and those that are serious attempts to avoid inherent dangers of the product.

3. Liability for breach of protective law, § 823 II *BGB*

Product liability may also arise as tort liability under § 823 II *BGB*.

§ 823 II *BGB* provides:

> The same obligation is imposed upon a person, who infringes/ breaches a statutory provision intended for the protection of others. If, according to the provisions of the statute, an infringement is possible even without fault, the duty to make compensation arises only in the event of fault.

Under this provision, a person who breaches a protective law (*Schutzgesetz*), which is intended for the protection of others, is liable for any damage arising from the infringement. The term "*Schutzgesetz*" mainly refers to statutes whether part of public, criminal or private laws, governmental decrees, local by-laws, or food and drugs

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[67] Landscheidt, at 51; for an English explanation, see Waddams, at 45.
[68] Question raised by Waddams, at 45.

regulations.[69] The law in question must have been "intended for the protection of others". Whether or not the particular plaintiff is included within the protective ambit of the violated statute depends upon its interpretation in light of the legislative intent.[70] The statute must have been designed to protect the victim as an individual, or as part of certain groups of individuals, rather than as a member of the public at large. In addition, the statute must have been designed to prevent the type of damage suffered by the victim. The creation of an individual claim must appear meaningful, sensible and tolerable in light of the whole system of liability.[71] In a claim based on § 823 II *BGB* the plaintiff has to prove the negligent or intentional violation of a protective law, and the causal connection between the violation and the damage. § 823 II *BGB* also requires the defendant's fault - just as is required under § 823 I *BGB* - in violating a protective law. Liability under § 823 II *BGB* may overlap with liability under § 823 I *BGB* or some other provisions within or outside the Civil Code (*e.g.*, liability under Pharmaceutical Products Act (*Arzneimittelgesetz-AMG*)). However this does not mean that the requirements of liability are the same in all cases. For example, § 823 II *BGB* can be more favorable to the plaintiff in two respects. First, whereas § 823 I *BGB* does not provide for compensation for purely pecuniary damages, such compensation may be awarded under § 823 II *BGB* if the statute violated covers pure economic loss. Secondly, although liability under § 823 II *BGB* is based on fault, case law in the Federal Supreme Court has also recognized an alleviating mechanism (*Beweiserleichterungen*) for proof of fault with the help of the *prima-facie* rule (*Anscheinsbeweis*) and has even reversed the burden of proof and placed

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[69] Thomas in: Palandt, *BGB* § 823 para. 140 at 932.
[70] Thomas in: Palandt, *BGB* § 823 para. 141 at 932 f.

it on the defendant, if the objective violation of the particular protective statutory duty by its terms is clearly established.[72] In this case, fault will be presumed unless the defendant can disprove it[73] (*e.g.*, by proving that the violation of the protective law was unavoidable) so that in this situation basing the claim on § 823 II *BGB* can be more favourable to the plaintiff than basing it on § 823 I *BGB*.

§ 823 II *BGB* comes into play concerning product liability cases, to the extent that a protective law exists covering a particular product, usually a risk-inherent one.[74] The Pharmaceutical Products Act, especially § 5 AMG - the prohibition against marketing unsafe or precarious drugs - has been recognized as a protective law within the meaning of § 823 II *BGB*.[75]

Similarly, we can classify as "protective laws" the prohibition in respect of substandard quality or misleading designations of drugs in § 8 AMG, as well as regulations about the labelling of pharmaceuticals in § 10 AMG, the package inserts in § 11 AMG,[76] and the expert information in § 11a AMG. The same is true of § 1 AMG, which lays down the intention of the Pharmaceutical Products Act to guarantee safety concerns arising out of the trade in drugs in connection with those regulations referring to the law of marketing authorization, which intend to ensure the quality and efficacy of pharmaceuticals.[77] Just as § 5 AMG is supposed to ensure the supply of safe pharmaceuticals, these regulations

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[71] 66 *BGHZ* 388 at 390.
[72] Thomas in: Palandt, *BGB* § 823 para. 174 at 937.
[73] *BGH* NJW 1968, 1279 at 1281; 51 *BGHZ* 91 at 103 f. - "fowl pest"; Thomas in: Palandt, *BGB* § 823 para. 203 at 943.
[74] Thomas in: Palandt, *BGB* § 823 para. 203 at 943.
[75] *BGH* NJW 1991, 2351 at 2351; Thomas in: Palandt, *BGB* § 823 para. 145 at 933, para. 203 at 943; Kullmann, [1983] Pharma Recht at 198.

are supposed to guarantee the supply of effective pharmaceuticals. Like § 5 AMG these regulations are designed for the protection, at least *inter alia*, of the ultimate consumer of pharmaceuticals. The purpose of the regulations is: (1) to make possible a therapeutic treatment by bringing effective pharmaceutical products onto the market, and (2) to avoid at the same time any protraction of the sickness, or the possibility that it will not be treated in a therapeutically efficient manner, or indeed not treated at all.[78]

4. Causation

The major problems the plaintiff faces in product liability cases based on § 823 I *BGB* are to show and prove the causal connection. The duty to compensate for damages requires that the damage was caused by the event that created the obligation to provide for compensation. The tortfeasor's conduct needs to be shown to be causal to the damage.[79] Therefore the plaintiff according to German liability law has to show and prove causal connections on different levels. First, that the defendant's conduct has caused his

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[76] See detailed explanation from Kullmann, [1983] Pharma Recht at 198 f.

[77] Hart in: Hart et al., at 156.

[78] Kullmann, [1983] Pharma Recht at 198 f.; Hart in: Hart et al., at 157. Insofar as liability for pharmaceutical products under the provision of § 823 II *BGB* can even be considered in cases, where injury is caused to a person, because a hypothetically possible, effective and efficient therapy with drugs failed by treating a sickness with an ineffective and inefficient product. In this case the damage would be caused by the pharmaceutical manufacturer's breach of the duty, following from the protective purpose of the particular provision under the Pharmaceutical Products Act, to produce only efficient drugs and would therefore fall within the ambit of the protective law. However, liability for inefficient products could only be imposed on the pharmaceutical manufacturer if the non-treatment due to the inefficacy of the product caused avoidable damage, *i.e.*, in cases where a person is already injured or sick, if "further" damage, in the sense of not being cured because the product is useless, due to the inefficient product that prevented effective therapy, could have been avoided by treatment with an efficient product. If the pharmaceutical product is useless because a higher dosage would have been required, or for any other reason not resulting from the drugs ingredients, an instruction defect is considerable. The question, if ineffective drugs can lead to the pharmaceutical-manufacturer's liability, will be discussed later.

[79] Helmut Heinrichs: in Palandt, *BGB Vorbem v.* (preliminary remark prior to) § 249 para. 54 at 252: hereafter cited as Heinrichs: in Palandt.

violation of or interference with the plaintiff's "absolute right" or interest protected by § 823 I *BGB* (*Rechtsgutverletzung*); this is the causation that gives rise to liability, the so-called causal connection constituting actionability (*haftungsbegründender Zurechnungszusammenhang*).[80] This is systemically an actual part of liability law and not the law of damages.[81] In the case of a product liability claim, strictly speaking a causal connection needs to be shown in two different perspectives, namely between the product's defect and the breach of the manufacturer's required duty of care[82] and also between the product's defect or the instruction defect and the violation of the plaintiff's "absolute right"[83]. Additionally, German law draws a distinction between this causal connection just discussed and a second connection, which is rather considered as part of the law of damages: a causal connection between the liability reason (violation or interference with the plaintiff's "absolute right") and the damage suffered or restitutionable detriment, the so-called causal connection completing liability (*haftungsausfüllender Zurechnungszusammenhang*).[84] The purpose of analyzing causation is to eliminate all those events from further consideration that were not caused

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[80] For an explanation in English see Vieweg in: Ebke/ Finkin, at 105.

[81] Heinrichs in Palandt, *BGB Vorbem. v.* § 249 para. 55 at 252.

[82] The causal connection between the breach of a duty of care and the product defect in general only plays a minor role in product liability processes, as this part belongs to the area of exonerating evidence, which is on the manufacturer, according to the "fowl pest" decision at least in cases of design and manufacturing defects, because the product defect normally has its origin within the manufacturer's business organization and risk.

[83] Regarding this aspect of causation the product liability case law jurisdiction has developed special principles concerning the burden of proof in cases of instruction defects in comparison with others. This will be discussed later in the appropriate context.

[84] For an explanation in English see Vieweg in: Ebke/ Finkin, at 205. In German law both causal connections can overlap in the individual case, *e.g.*, when a defective erected house collapses, in the owner's (customer's) claim under "*positiver Vertragsverletzung*" (positive breach of contract for work) his bodily injury belongs to the causal connection completing liability, whereas the possible liability claim to be considered under §§ 823, 847 *BGB* or the body injury of a visitor (not party to the contract for work)

by the proceeding in question, or by the event, and therefore cannot be considered as its consequence.

Within these causal connections the German law of torts applies a two-stage inquiry to problems of causation. The first stage asks whether the defendant's conduct played some role in bringing about the plaintiff's injury. As a possible cause in this sense is considered: each conduct in view of the *haftungsbegründende Kausalität* and each violation of a protected interest, which cannot be ignored unless the result in question - *i.e.*, violation of interests or damage - would disappear in view of the *haftungsausfüllende Kausalität.*[85] This means, causation in fact is assumed, if a part of the defendant's conduct has been a *conditio-sine-qua-non* of the plaintiff's injury, which basically corresponds to the "but-for" test in common law jurisdiction, *i.e.*, if the harm would not have occurred "but for" the conduct of the defendant ("*Äquivalenz* -theory")[86].

However, the "*Äquivalenz* -theory" test is not alone sufficient to assess causation. Therefore the second inquiry checks which of the numerous conditions in the harm will also be treated as its legal cause. This question of causation in law applies the theory of adequate cause ("*Adäquanztheorie*"[87]). As to this two-stage approach, no fundamental

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concerns the causal connection constituting actionability; Heinrichs in: Palandt, *BGB Vorbem. v.* § 249 para. 56 at 252.

[85] Kullmann in: Kullmann/ Pfister, Kza. 1525 at1.

[86] Heinrichs in: Palandt, *BGB Vorbem. v.* § 249 para. 57 at 252; for an English explanation see Vieweg in: Ebke/ Finkin, at 206.

[87] What is at issue, in both the jurisdiction and the scholarly literature, is weather the question of adequate cause can still be considered relevant in product liability cases. The newer tendency is to require, beyond analysis of the adequacy of causation, if the damage occurred is still within the range of the protective purpose of the breached law (*Lehre vom Schutzzweck der Norm*), Kullmann in: Kullmann/ Pfister, Kza. 1525 at 3-5.

differences exist between German and the Canadian law.[88] Under the theory of adequate causation, causation in law is excluded if the damage is not an adequate consequence of the tortfeasor's conduct. An event is regarded as an adequate cause if it has materially increased the objective possibility of a consequence of the kind that actually came about. In order to determine this, all circumstances recognizable by an expert at the time the event occurred and, in addition, all circumstances known to the originator of the condition at the time of its entry have to be taken into consideration. In contrast, the Anglo-Canadian doctrine of remoteness of damage requires the damage to be foreseeable to a reasonable person. However, German, English and Canadian courts can arrive at the same conclusion simply by narrowing or widening the scope of what is regarded as foreseeable or adequate.[89]

Because almost every course of events, however abnormal, may be foreseeable for the "optimal" observer, the theory of adequate cause, just as the *"but-for"* test, does not suffice as a corrective device for limiting the very extensive scope of liability. Hence the theory of adequate cause is combined with a more normative theory of causation, the so-called scope-of-the-rule theory (*Lehre vom Schutzzweck der Norm*[90]), which is supposed to exclude damage which is too remote. This theory poses the question: whether the damage still lies within the scope of consequences, which were meant to be compensated under the particular law in question, or which it was meant to prevent. Consequently, damage cannot be recovered if harm caused by the tortfeasor is not within the ambit of

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[88] Vieweg in: Ebke/ Finkin, at 206.
[89] Vieweg in: Ebke/ Finkin, at 206.
[90] Heinrichs in: Palandt, *BGB Vorbem.* v. § 249 para. 62 at 253.

the protection aimed at by the rule in question (*Schutzzweck der Norm*)[91].[92] This applies where the harm is not the mischief which the statute was designed to prevent, or if it has not come about in an unlawful manner, also known as the connection of unlawfulness (*Rechtswidrigkeitszusammenhang*).

The view point of the "rule's (protection) purpose" (*Normzweckgedanke*) serves the purpose of a general restriction of liability under § 823 *BGB*, which provides a fairly comprehensive protection regarding those objective rights legally protected by it. Therefore even the application of the scope-of-the-rule theory can actually lead to a restriction of liability only in a few cases. But as those cases do exist, in the case of compensation claims based on § 823 I *BGB*, it generally has to be examined, whether the damaging event's consequences fall within the ambit of protection aimed at by the rule in question. However, as far as a delictual legal duty to avert danger exists and is not met, the damage resulting from that, as a general rule, lies within the scope of protection provided by § 823 I *BGB*.[93]

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[91] For detailed explanation, see Kullmann in: Kullmann/ Pfister Kza. 1525 at 4 ff.

[92] An example of the exclusion of compensation by use of this theory is provided in a decision where the Federal Supreme Court held that the defense costs incurred by the victim of a traffic accident in criminal proceedings related to this accident could not be covered under § 823 I *BGB*. The court opined that these costs had nothing to do with the personal injury and property damage suffered through the accident, but arose from the victim's being suspected of committing a criminal offence and from the decision of the prosecuting authority to institute proceedings against him. The Court held that the risk of becoming involved in criminal proceedings and having to spend money in defending oneself was a general risk that affected every citizen and that it was not a risk the law intended to avert by the protection of health and property provided by § 823 *BGB*; example given by Vieweg in: Ebke/ Finkin, at 206 f. referring to 27 *BGHZ* 137 at 140 ff.

[93] But there are exceptions to this principle especially in the field of product liability law, *e.g.*, above all the breach of the duty to give instructions or warn, Kullmann in: Kullmann/ Pfister, Kza. 1525 at 4 f.; this will be dealt with later.

5. Fault

Furthermore the plaintiff has to show and prove the defendant's fault. The tortfeasor is responsible in German delict law for intentional conduct as well as negligence. The focus here is upon the product defect caused by the manufacturer's negligence, as one can ordinarily proceed on the assumption that the pharmaceutical manufacturer will not intentionally breach the consumer's property and safety interests (*Integritätsinteresse*).[94] According to § 276 I S. 2 *BGB* "a person who does not exercise the required ordinary care acts negligently". This means that the law first of all requires an objective standard of care, the so-called "external" or objective duty of care (*"äußere"* or *objektive Sorgfalt*[95]), assessed in relation to the abstract standard expected from an ordinary person in the same situation. In general this standard demands that everybody act in accordance with the standard of his category of people[96] in the same profession or age-group.[97] If the violation of *"Verkehrssicherungspflichten"* (the duty of care) in product liability cases is at issue, the standard or conduct required by the duties coincides with the standard described above, because the scope of the *"Verkehrssicherungspflichten"* is governed by a duty of care measured according to § 276 I S. 2 *BGB*. This means that if the

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[94] Kullmann, [1983] Pharma Recht at 197.

[95] In the case of violation the term *"objektiver Pflichtverstoß"* or just *"Pflichtwidigkeit"* (conduct objectively contrary to the required duty) is used. This is one side - the external besides the internal - of "fault", if the tortfeasor's negligence stands in question. It also corresponds with the violating conduct, in the case of product liability cases the breach of the duty of care, which is "indicated" by way of the objective defectiveness of the product. Hans Josef Kullmann, *"Die neuere höchstrichterliche Rechtsprechung zur deliktischen Warenherstellerhaftung"* [1981] Wertpapier-Mitteilungen 1322 at 1330: hereafter cited as WM.

[96] Erwin Deutsch, *"Grundmechanismen der Haftung nach deutschem Recht"* [1968] Juristenzeitung 721 at 723.

[97] Kullmann in: Kullmann/Pfister, Kza. 1525 at 18.

"Verkehrssicherungspflichten" are complied with, then at the same time the objective standard of care required by § 276 I S. 2 *BGB* is met as well.

Should it be the contrary, that a violation of the *"Verkehrssicherungspflichten"* has been established, one then needs to inquire if the tortfeasor has also not met the required so-called "internal" or subjective duty of care (*"innere"* or *subjektive Sorgfaltspflicht*[98]).[99] That is because fault in German delict law is conditional upon the tortfeasor's personal responsibility for his conduct; *i.e.* it needs to be questioned, if he can from a subjective perspective be blamed for his conduct. This means that to establish fault one needs to look at the particular person, to find out if under consideration of his duty of care he could have foreseen or recognized that a precautionary action was required from him. This is so, even though in a lot of cases a conclusion might be drawn from the fact that the manufacturer has objectively violated his duty of care, which possibly also suggests the violation of his subjective duty of care.

The distinction between the objective and subjective duty of care is of great importance in product liability cases when, for example, according to the standard of the scientific and technical knowledge of the time when the product was distributed, it would have already objectively been recognizable that a product was defective; but in the individual case the manufacturer cannot be held responsible or cannot be blamed for that because, from the

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[98] Here there is much talk about the "inner" or "subjective" side of the conduct, which refers to the ability or possibility of the tortfeasor to recognize the appropriate conduct in each individual case. The question here is, can the *Pflichtwidrigkeit* be imputed to the tortfeasor? This side of negligence is what actually constitutes *Verschulden* (fault).Hart in: Hart et al., at 152; Hans Josef Kullmann, *"Die Rechtsprechung des BGH zum Produkthaftsplichtrecht in den Jahren 1995 - 1997"* [1997] Neue Juristische Wochenschrift 1746 at 1753: hereafter cited as NJW.

[99] Kullmann in: Kullmann/Pfister, Kza. 1525 at18.

subjective point of view, this standard of experience or knowledge was for whatever reason not recognizable for or known by him.

In contrast to the explanations concerning the condition of fault given above, under § 823 II *BGB*, the plaintiff is only required to show the defendant's fault in the sense of adverting to his violation of the protective law. In contrast to the situation under § 823 I *BGB* the manufacturer's fault in regard to § 823 II *BGB* in general is not required to relate to the concrete violation of the "absolute right".[100]

6. The onus or burden of proof

Generally in German law everybody who asserts a claim seeking compensation in a law suit, has to be able to prove all the elements constituting the liability of the other party. This means in product liability cases that the plaintiff has to prove that the product or the instruction about the product's use was objectively defective, that the manufacturer has brought the product into public circulation with the defect or with defective or insufficient instruction, and that the defect caused the damage. Furthermore the court has to be persuaded that the manufacturer has at least negligently breached its duty of care and therefore has culpably caused the damage that has actually occurred.[101] In this context it is especially important to determine which party to the law suit has the burden of proof for each fact, which corresponds with the legal obligation: here provided by § 823 I *BGB*, as mentioned above. This is because whenever certain facts cannot be clarified in the

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[100] *BGH* [1955] VersR 504 at 505; *BGH* [1971] VersR 239 at 241 = [1971]NJW 459 at 461.
[101] Kullmann in: Kullmann/Pfister, Kza. 1526 at 2.

legal proceedings or an allegation cannot be proven, *i.e.*, if the basic facts for consideration as evidence cannot be unambiguously determined, the court needs to be aware of whether the burden of proof rests with the plaintiff or with the defendant: in other words, which of them has to carry the risk of unprovability?[102] This is decisive because, in an unprovable situation, that will be the party who loses the case.

In the field of product liability the jurisprudence of the Federal Supreme Court has developed several alleviating mechanisms in favour of the injured party. The task of proof has been made easier for him from several perspectives.

Often the courts come to help with the so-called *prima-facie* evidence rule (*"Anscheinsbeweis"*). However, this is only possible if the question of evidence concerns a typical course of events, which upon consideration of general principles founded on experience, whether ordinary human experience or common scientific experience, tends affirmatively to show a product defect or a causal connection and therefore fully justifies the judge's conviction to impose responsibility to the full extent.[103] It is then on the defendant manufacturer to show facts that are sufficient to raise seriously the possibility of another interpretation of events. In this way the *prima-facie* evidence would be rebutted (*erschüttert*) and the injured party would be required to give full evidence. However, even though the *prima-facie* rule is applied to the different stages of giving proof wherever possible, such as in showing that the product was defective and that the defect arose out of the manufacturer's business and that it caused the injury which

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[102] Kullmann in: Kullmann/Pfister, Kza. 1526 at 2.

resulted in the damage claimed, it is still difficult for a plaintiff to prove his claim for other reasons. These cannot be explained here in every detail because the actual product defect is not the major focus of this paper. The relevant problems that arise specifically out of the manufacturer's instruction duty and his duty to warn will be discussed at each point where they need to be considered.[104]

For proof of the manufacturer's fault caused by its negligence, the injured party has, according to the explanations given above, to prove the breach of the "external" as well as the "internal" duty of care.[105] Originally the case law jurisprudence - as with the situation of proving a defect and causation - came to help here as well, with the *prima-facie* rule. Subsequent case law, however, has improved the plaintiff's position by reversing the burden of proof for the manufacturer's fault, *i.e.*, the breach of his internal and external duties of care, provided the plaintiff on his part is able to prove that the damaging event was caused by an objective product defect that already existed when it left the manufacturer's business.[106] The precondition for this reversal of the burden of proof is that the plaintiff proves to the satisfaction of the court that the product was defective at the time of distribution, *i.e.*, that it contained a manufacturing or design defect which caused his damage.[107] Then it is on the defendant manufacturer to prove that

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[103] Kullmann in: Kullmann/Pfister, Kza. 1526 at 3.
[104] See chapter IV., 5., "The Burden of Proof".
[105] 80 *BGHZ* 186 at 196 f. - "apple-scab I" - referring to 51 *BGHZ* 91 at 104 ff. -"fowl pest". In the first instance unclearness existed in literature, if the reversal of the burden of proof only referred to the "subjective" side of the entire actual facts or if it also referred to the "external" duty of care and with that would include the "objective" conduct, contrary to the required duty. With the "apple-scab I" decision, the Court made expressively clear that it referred to both sides (*Pflichtwidrigkeit* and *Verschulden*).
[106] 80 *BGHZ* 186 at 196 - "apple-scab I" referring to 59 *BGHZ* 303 at 309, originally determined in 51 *BGHZ* 91 at 105 "fowl pest".
[107] Kullmann in: Kullmann/ Pfister, Kza. 1526 at 24.

it did not breach its duty of care, because it is a duty not to produce and distribute hazardous or defective products.[108] This is because the manufacturer is better able to provide evidence of the course of events that happened in its scope of risk and organization during the period of manufacturing. It is easier for him to explain and prove the facts and details that may possibly have caused the defect and that might not be due to his fault as, for example an unavoidable development defect, that was unforeseeable according to the standard of technical and scientific knowledge of the time. If the manufacturer is not able to give evidence as to the cause of the defect, the cause for this undemonstrability rests in the range of his business risk. Therefore it is appropriate and reasonable that he has to carry the risk of undemonstrability of his absence of fault. These principles for reversing the burden of proof concerning the manufacturer's fault in regard to manufacturing and design defects, developed by the Federal Supreme Court through case law, have their origin in the so-called "fowl pest" case, which will be explained in its important aspects, in the following section[109].

7. Unlawfulness (*Rechtswidrigkeit*)

§ 823 I *BGB* further requires the "absolute right" to have been injured *rechtswidrig* (unlawfully). The traditional view, which is the classical one still prevailing with the courts and most scholars, is that the mere violation of one of the rights or interests enumerated in § 823 I *BGB* establishes a presumption of unlawfulness. According to this

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[108] Rolland, at 375.
[109] See, under III.

view, unlawfulness depends on the harmful result (*Erfolgsunrecht*).[110] Consequently, in principle when the provisions of the *actus reus* are materialized (*Tatbestandsmäßigkeit*) the unlawfulness is indicated.[111] However, unlawfulness can be excluded under certain circumstances that establish a ground of justification. Examples of such a legally recognized defense (*Rechtfertigungsgrund*) are self-defense (*Notwehr*) § 227 *BGB*, *i.e.*, an action taken in order to repel an actual unlawful act upon oneself or another person, also *Notstand* (urgent necessity) § 228 and § 904 *BGB* and consent (*Einwilligung*).[112]

III. Case law developing product liability based on the delict law of negligence

1. The "fowl pest" case (*"Hühnerpest"-Fall*)

With the so-called "fowl pest" case the Federal Supreme Court rendered what has regarding various respects become a landmark decision in the judicial development of product liability.

The plaintiff, who ran a poultry farm, had her chickens vaccinated against fowl pest by a veterinarian. A few days later, fowl pest broke out. More than 4000 chickens died and over 100 had to be slaughtered. The plaintiff claimed compensation for the damage from

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[110] A newer approach defines unlawfulness by looking at the conduct itself (*Handlungsunrecht*) instead of the result of the conduct. According to this, the defendant's conduct is only unlawful if it has either failed to measure up to the standard of conduct imposed by a particular imperative rule applicable to the occasion in question (*Verhaltensnorm*) or if it has violated the general duty of care (*allgemeine Sorgfaltspflicht*) imposed upon all persons to take care not to injure others, Thomas in: Palandt, *BGB* § 823 para. 33 at 915.

[111] Exceptions are *inter alia* the violation of some of the additional provisions, such as "right of an established and operating business" ("*Recht am eingerichteten und ausgeübten Gewerbebetrieb*") and "general right to privacy" ("*allgemeines Persönlichkeitsrecht*"), because in this case it needs to be positively established, if the damage causing conduct for itself has violated societal conventions (*gesellschaftlicher Rücksichtnahme*), Thomas in: Palandt, *BGB* § 823 paras. 33 f. at 915 f.

the defendant vaccine manufacturing company, whose vaccine had been used by the veterinarian. This he had acquired in bottles from the defendant. When a few days later the veterinarian inoculated the chickens on another farm, fowl pest broke out there as well. The same happened at about the same time to three other poultry breeders who had had their chickens inoculated with the defendant company's vaccine from the same batch. An examination of the bottles revealed that the vaccine contained bacterial impurities and active viruses that had not been sufficiently immunized and that some bottles were not sterile.

The defendant company disputed the assertion that the outbreak of the fowl pest was to be traced to the use of its vaccine or that the defective sterility of the bottles used by it was or could have been the cause. The defendant also supplied evidence tending to exonerate it from liability for its staff.

Until 1968, product liability claims under § 823 I *BGB* failed in most cases, because the plaintiffs could not prove the defendants' fault. To support the idea of consumer protection, scholars had developed several contractual and quasi-contractual theories to make the manufacturers of defective goods liable to the ultimate consumer, although a direct contract between the manufacturer and the ultimate consumer usually does not exist.[113] However the Federal Supreme Court did not recognize these approaches, as in principle the only person who can claim compensation for damage under a contract is the one who is a party to the contract, to whom the damage occurred in fact and who, in law,

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[112] Vieweg in: Ebke/ Finkin, at 207.
[113] For an overview of further details see 51 *BGHZ* 91 at 93 ff. - "fowl-pest".

has to bear that loss or damage.[114] The court also came to the conclusion that the principles which under exceptional circumstances sometimes allow a third person, who is not a party to the contract, to claim contractual compensation for suffered loss and damages, do not usually apply in the relationship between the manufacturer and the ultimate consumer.[115] The court stated that if damage occurs to a third party, the tortfeasor can be held liable to him - apart from certain exceptions - only in delict.[116]

Furthermore the decision in the "fowl pest" case is of far-reaching importance, because it was the first product liability case to apply a new alleviating mechanism (*Beweiserleichterungen*) that the courts had recognized for the production of evidence favouring the plaintiff of a defendant's liability; namely the reversal of the general principle of the burden of proof concerning the manufacturer's fault.[117]

As mentioned above, the difficulty with § 823 I *BGB* in product liability cases was that the ultimate consumer (*i.e.*, the plaintiff) had to prove the manufacturer's fault. This was difficult because a product defect generally arises out of activities inside the manufacturer's business, which are difficult for the plaintiff to access for documentation. To get around this problem the courts for a long time helped the injured party by contenting themselves with proof of a chain of causation which, according to human experience, would tend to indicate an organizational fault (*Organisationsverschulden*) by the manufacturer in the production process. This invocation of a *prima-facie* rule (*Anscheinsbeweis*) did not markedly improve the plaintiff's situation, since all too often

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[114] 51 *BGHZ* 91 at 93.
[115] 51 *BGHZ* 91 at 93 ff., for further explanation of these approaches in English language see Markesinis, at 71-76.
[116] 51 *BGHZ* 91 at 93.

the owner of a business was able to show that the defect in the product might have been caused in a way that did not point to his fault, evidence which generally relied on activities inside his business which were difficult for the injured party to disprove. Thus, in most cases the plaintiff was not able to prove the manufacturer's fault because he could not know what exactly had happened during the manufacturing process. Consequently, the Federal Supreme Court came to the conclusion that, when damage has arisen within the range of the manufacturer's business risks, he cannot be regarded as exonerated merely because he points out that the defect in the product might have arisen without any organizational fault of his; he must, on the contrary, supply positive and complete evidence that the defect in the product is not due to his fault.[118] This means that all that the plaintiff has to prove in product liability cases is that the defendant's product was defective when it left his place of business and that the defect caused the plaintiff's injury. Although the decision did not introduce strict liability for defective products, the reversal of the burden of proof extends the scope of liability for fault under § 823 I *BGB* in such a way that, in practice, it is not very different from strict liability.[119]

Based on this decision the courts have continuously developed the different categories of product defects shown above.

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[117] 51 *BGHZ* 91 at 105 ff.
[118] 51 *BGHZ* 91 at 104 f.
[119] Vieweg in: Ebke/Finkin, at 218.

2. The principles found in the decision[120]

The *BGH* came to the conclusion that the vaccine supplied by the defendant company was defective and caused the disease in the chickens. The court also found the defendant company liable under § 823 I and II *BGB* and laid down the following principle for product liability cases[121]:

> If anyone when using an industrial product for its declared purpose suffers injury in one of the legal interests protected by § 823 I BGB, through the defective manufacture of the product, it is for the manufacturer to explain the antecedent course of events that caused the defect and thereby to show that he was not to blame for it.

In this way the court explains that it is beyond dispute that even in "product liability" the injured party must prove that the damage was caused by a defect in the product. In the view of the court the plaintiff had therefore to prove that the fowl pest broke out among its chickens because the vaccine originated with the defendant company and contained active viruses when delivered. As a result that proof was considered by the court - in concurrence with the findings of the Court of Appeal - to have been provided. In so doing the court basically followed the explanations in an expert's opinion, according to which the contamination of the bottles by bacteria probably caused a reactivation of the virus. The expert had also declared it highly probable that the bacteria had found their way into the bottles at the time of manual pouring of the vaccine from the large containers into the bottles, and had even held it possible that the contamination of the vaccine was caused by

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[120] 51 *BGHZ* 91 at 102 ff.
[121] 51 *BGHZ* 91 at 102.

"human error" on the part of one of the persons employed by the defendant company in bottling the vaccine.[122]

With regard to the defendant's fault the court declared the following:[123]

> 3. ... It is indeed correct that the Court of Appeal considered no fault of the defendant company itself to have been proved. It rather accepted only that it was probably an employee who was to blame for the damage. The liability of the defendant company, cannot, as we have seen, be established by applying the law of contract, as set out in § 278 BGB. That does not, however, necessitate sending the dispute back to the judge of fact. For it would still be for the defendant company to exonerate itself even if the plaintiff can only base her claim on § 823 BGB.
> aa. This results already from the fact, that the plaintiff's claim for compensation is also based on § 823 II BGB. For the defendant company, by delivering the dangerous bottles of vaccine, infringed a protective enactment. This vaccine, a pharmaceutical product within the meaning of the Pharmaceutical Products Act of 16 May 1961 (§ 3 III AMG)[124], was capable of producing in the chickens injurious, even fatal, effects. § 6 AMG[125] prohibits the putting of such vaccines into circulation. This provision ...constitutes an enactment for the protection of endangered human beings or animals. If, however, an infringement of a protective enactment is proved, it is presumed to be the result of fault. The infringer therefore must produce and prove facts sufficient to disprove his fault. The owner of a business (or the manufacturer) did not produce that proof so long as a possible cause, falling within the scope of his responsibility and which might point to fault, remained unelucidated.
> bb. This rule governing the burden of proof would, however, also apply if the plaintiff could base a claim for damages only on subsection I of § 823 BGB. In that case also it would be for the defendant to exonerate himself. It is true that the injured party who relies on § 823 I BGB will have to allege and if necessary will have to prove not only the causal connection between his damage and the conduct of the tortfeasor, but also his fault. However, the possibility of proving the subjective conditions depends appreciably on how far the injured party can elucidate the details of the objective course of events. That is however especially difficult when it relates to antecedent events which played a part in the business during (the process of) manufacturing the product. The courts for a long time came to the help of the injured party by contenting themselves with proof of a chain of causation , which, according to human experience, indicates an organizational fault of the manufacturer. All the same, one cannot stop at this point in considering claims for damages (Schadensersatzansprüche) for "product liability". All too often the owner

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[122] 51 *BGHZ* 91 at 102 f.
[123] 51 *BGHZ* 91 at 103 ff; English translation based on Markesinis, case 27 at 351 ff.
[124] Now § 2 I, § 4 IV *AMG*.
[125] Now § 5 *AMG*.

of a business can show that the defect in the product might have been caused in a way that does not point to his fault - evidence which generally relies on activities in his business and which is difficult for the injured party to disprove. In consequence, when damage has arisen within the range of the manufacturer's business risks, he cannot be regarded as exonerated merely because he points out that the defect in the product might have arisen without any organizational fault of his; he must, on the contrary, supply positive and complete evidence that the defect in the product is not due to his fault. This is required in the area of "product liability" in order to protect the interests of the injured party - whether ultimate consumer (Endabnehmer), user, or third party; on the other hand, the interests of the producer allow him to demand that he may prove his lack of fault (Nachweis seiner Schuldlosigkeit).

This rule of evidence indeed only operates as soon as the injured party has proved that his damage falls within the scope of the manufacturer's organization and risks, in that it was called forth by the existence of an objective defect (Mangel) or a situation which did not meet the required duty of care (Zustand der Verkehrswidrigkeit). This proof is required of the injured party even when he sues the author of the damage for breach of protective and subsidiary duties arising from a contract or the negotiations for one (citations omitted). It is the same, if he claims against the product manufacturer for breach of his duty of care. However, once he has provided this evidence, the product manufacturer is better able to explain the facts or to bear the consequences of being unable to give proof of his own explanations. He surveys the field of production, determines and organizes the manufacturing process and the control of delivering the finished products. The size of the business, its complicated, interlocked, departmentalized organization, its involved technical, chemical, or biological processes and the like make it practically impossible for the injured party to ascertain or resolve the cause of the defect. He is therefore unable to lay the facts before the judge in such a way that he can decide with certainty whether the management is to be blamed for failing or whether it is a case of a mistake in manufacture for which a workman is at fault, or a single breakdown (so-called "Ausreißer") that may happen at any time, or a defect in development that was unforeseeable in the existing state of technology or science. But if the cause of unexplainability lies within the scope/ area of the manufacturer, it is also within the sphere of his risk. In this case it is appropriate and expected of him that the risk of not being able to prove his innocence should lie with him.

Such rules of evidence have always been recognized by the jurisprudence in contractual or quasi-contractual relations of a special legal character between injured party (creditor) and author of damage (debtor). There is no obvious reason that can be given why this rule of proof should not also apply to liability cases that are to be decided according to the law of delict, if the reasons the rule is based upon also apply in this case. In certain contexts § 831 BGB already imposes on the employer the proof of exoneration - the similar applies to liability cases according to §§ 832, 833, 834 BGB, and above all to §§ 836 ff. Here, it is true, the law requires a person damaged through the collapse of a building to prove that the damage was " the consequence of defective erection or insufficient maintenance", but lays on the possessor etc. the burden of proving that he had done everything to avoid the/ any dangers that could arise in relation to his building. The reversal of the burden of proof directed in these provisions does not always proceed from a presumption of fault in the tortfeasor. It rests rather in the main on the thought that the tortfeasor is in a better position than the injured party to throw light on the events relevant to the charge of negligence, so that it is just to impose on him the risk of being unable to

> do so. The Senate has already in its judgment of 1 April 1953 (VI ZR 77/52) indicated that the plaintiff cannot be required to prove, which as a rule would be an almost impossible task, that the damage causing thing came into circulation through the fault of the owner of a business or his agents. Above all, the Senate has already in its judgment of 17 October 1967 (VI ZR 70/66) declared that it is for the manufacturer to exonerate himself, if the injured party can give no details about the specific management's culpable breaches of duty. The modern development of production, involving persons and machines that are hard to identify at a subsequent stage and rests on finishing capable of being inspected and controlled only by specialists, demands a development of the law of evidence in the direction already indicated in § 836 BGB ....
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> But in this connection - as with the recognized shifting of the burden of proof for positive breaches of contract (positive Vertragsverletzungen) - it always depends on the interests at stake in the respective case group under consideration. The question whether the assumption of the risk of proof can be imputed in the case of the owner of a small business, where the manufacturing process can be easily surveyed and examined (family and one-man business, agricultural producers, and the like), need not be considered here. In cases of the present kind it is in any case for the manufacturer to exonerate himself.

In the "fowl pest" case the defendant company was not able to furnish that proof of exoneration.

With this decision the "fowl pest" case became the leading case effecting a reversal of the burden of proof in the case of manufacturing defects. According to the reasoning of the court the manufacturer must prove that he is not at fault, if a person or a thing suffers injury or damage because of his defectively manufactured product. In this case the injured party needs only to prove that his damage was due to an objective defect (*objektiver Mangel*) or to conditions that do not meet the required standard of care (*Zustand der Verkehrswidrigkeit*), by virtue of matters lying within the manufacturer's ambit of organization and risk (*Organisations- und Gefahrenbereich des Herstellers*).[126]

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[126] Confirmed by the Federal Supreme Court in 80 *BGHZ* 186 at 196 - "apple scab I".

Subsequent case-law has extended the application of these principles to cases of defective design.[127] However, regarding instruction defects, the principles for reversing the burden of proof have not been found applicable to the same extent as here, for different reasons. The special situation for the burden of proof apportionment in question, in the field of instruction defects, will be explained later, regarding instruction and warning duties of the pharmaceutical manufacturer.

IV. Case law concerning instruction and warning duties in the field of pharmaceutical product liability (and cognate areas)

The starting point for the following analysis is not a defect in the product itself. At this point we will look rather at dangers that arise out of using a product that is only safe when used with due regard to the instructions or warnings provided. The focus lies on pharmaceutical products and the manufacturer's duty of care concerning his instructional duties and his duty to warn about any risks inherent in his product's use. In Germany this field of pharmaceutical product liability is also based on case law and has been developed during recent years out of the product liability jurisprudence discussed above. However the first case in this line does not really belong to the civil law product liability jurisprudence at all, because it was decided by a criminal court on the occasion of a criminal proceeding against the manufacturers responsible for thalidomide products.

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[127] 67 *BGHZ* 359 at 362.

1. The starting point: the *"Contergan"*-Thalidomide case

The first case dealing with the pharmaceutical manufacturer's duty to give instructions about the inherent risks of a pharmaceutical product and his duty to warn was the Contergan-Thalidomide-case decided by the Provincial Court of Aachen (*Landgericht Aachen*). Considering the pharmaceutical manufacturer's duties, the decision laid special emphasis upon the degree of suspicion of hazardous side-effects, regarding pharmaceutical products which should give rise to a mandatory reaction on the part of the pharmaceutical manufacturer, to prevent serious danger to human health.

a. Facts and substantive background

Contergan is the trade-mark of Thalidomide. The sleeping drug Contergan was developed and manufactured by the German pharmaceutical company Chemie-Grünenthal, put on the market in Germany in 1957 and swiftly distributed throughout the world under different names. Shortly after that it turned out that Thalidomide probably caused severe side-effects in certain consumers. In particular, cases of nerve damage were reported. Later, in 1961 it was suspected to cause malformation, when several mothers gave birth to babies missing ears, legs, arms, or other limbs, after having taken the drug during certain months of their pregnancies. As a result all thalidomide containing products were taken off the market. On 27th May 1968 a criminal case in the Provincial Court of Aachen was launched against seven leading staff members of Chemie-Grünenthal, which was put to an end by the court's order to stay the proceedings on 16th December 1970.

Even though the case was dealt with in criminal proceedings the court's ruling is of high importance for the civil liability of pharmaceutical manufacturers in product liability

cases even to the present time. It is the first German decision that elaborated upon the concept of care in this specific case of danger-carrying conduct and laid down in detail the commandments for appropriate action during the time of drug distribution. The court's explanations referred to the pharmaceutical manufacturers' duties of care, especially concerning their duty to disclose information and their duty to warn physicians and consumers.

b. The decision[128] of the Provincial Court of Aachen (*Landgericht Aachen*)

The court's findings paid special attention to the pharmaceutical manufacturer's obligation to give full disclosure (*Offenbarungspflicht*) concerning dangerous side-effects of his products.

Here the court raised the question: "How is a proper and conscientious pharmaceutical manufacturer expected to react, if he receives information which raises the suspicion that harmful side-effects are being caused by the products he distributed?" Therefore the court stated in detail, precisely **when** - *i.e.*, under which circumstances - the pharmaceutical manufacturer has to take action after receiving such information; and following that, **which steps** he has to take.

The court took for granted, that the pharmaceutical manufacturer in general has an obligation to give full disclosure, if he is aware of harmful effects of his product. This

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[128] This decision was made by order of the court to stay the proceedings (*Einstellungsbeschluß des LG Aachen v. 18.12.1970)* in a criminal procedure against the responsible collaborators of the German pharmaceutical company Chemie-Grünenthal.

would follow out of the patient's right of self-determination, his right to decide whether he wants to agree to an interference with his health or bodily integrity.

The court drew a parallel to the physician's obligation to give full disclosure to his patients following from the same principle.

The court pointed out that this right is not only engaged when the harmful side-effects of a pharmaceutical product have been scientifically proved. If there are just and reasonable grounds for suspicion (*auf Grund eines ernst zu nehmenden Verdachts*) that it has to be feared that a drug also causes health damages, the consumer finds himself in a position where he has to make a decision, whether he wants to risk an interference with his body's integrity or not. This right of the consumer to make a decision results in a corresponding obligation in the pharmaceutical manufacturer to give full disclosure.[129]

According to the court's reasoning, the pharmaceutical manufacturer has a duty to protect the consumer on the ground of the specific nature of his products. During legal proceedings in the "*Contergan*" case, the expert witnesses explained with virtually complete consistency that no pharmaceutical product is without any unwanted harmful side-effects. All are, in Anglo-American legal terminology, "unavoidably unsafe products"[130]. Therefore the pharmaceutical manufacturer would, besides the benefits of his product, also create a certain source of danger. In the court's opinion a sufficient consumer protection would not be guaranteed if the manufacturer would only take steps

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[129] Observation: The duty to inform according to general product liability law might start earlier than under the provisions of the Pharmaceutical Products Act. Under § 84 S. 2 Nr. 2 *AMG*, above all things, the consumer ought to be informed about risks that are known from testing records or about which a certain awareness in medical science exists: Deutsch, at 604 para 912.

[130] Waddams, at 43; also Kullmann in: Kullmann/ Pfister, Kza. 3800 at 5.

when the harmful side-effects are evident, or if a suspicion about harmful effects has been scientifically proved. The court held that the manufacturer has to take appropriate actions as soon as the suspicion is supported by several serious reports (*aufgrund eines durch mehrere ernst zu nehmende Meldungen verstaerkter Verdacht besteht*).[131] This is because definite proof of the harmful quality of a pharmaceutical product can often only be furnished after a fairly long time, if indeed at all. Were the manufacturer allowed to wait until that time, the consumer's protection as a result would depend on if and how fast the evidence of the harmful effect can be shown. Under consideration of the consumer's legitimate interests, the court was of the view that the pharmaceutical manufacturer has to carry the risk of demonstrability, or persuasion (*Nachweisbarkeit*) of responsibility for the potentially harmful effects of his product during the time of abeyance. According to the court's opinion there can be no doubt that the consumer's interests, not to expose his health to damages caused by taking a drug, have priority over the manufacturer's interests in performing an unrestricted distribution of his product. To this extent health is considered to be the more highly valued interest.[132]

This suggested reallocation of risks to the disadvantage of the manufacturer takes into account that the pharmaceutical manufacturer is better able than the consumer to realize the risks involved. The consumer, who is not informed of possible side-effects of a product, does not know about the risks he might be exposed to when taking the drug. Therefore he has no chance to protect himself against possible health injuries. The

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[131] *LG* Aachen [1971] JZ 507 at 516.
[132] *LG* Aachen [1971] JZ 507 at 515.

manufacturer, on the other hand, is able to recognize a considerable part of the side-effects through careful examination of the product's substance and is able to restrict the intended use of the drug from the beginning, in such a way that the consumer will normally not be exposed to special risks later.[133]

In this way the court admits to the fact that sometimes the side-effects of pharmaceutical products are not recognizable by examination during the experimental and clinical phases, because they become revealed only after the product has been widely used by people. But in this case also, the court is of the view that the pharmaceutical manufacturer's risk is still lower than the consumer's. This is for the following reasons: the manufacturer, who takes appropriate action in response to possible dangers when his product is subsequently suspected to have harmful side-effects, might only risk a reduction in distribution and sales for the time being. The restriction took place for a good reason, if it turns out that the suspicion was correct. And even if the suspicion turns out to be wrong, the manufacturer only has to cope with temporary loss. The consumer on the other hand might have already suffered lasting health damages when the product in fact generated the suspected side-effects, before they could be considered scientifically proved.[134]

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[133] *LG* Aachen [1971] JZ 507 at 515 f.

[134] *LG* Aachen [1971] JZ 507 at 515 f. In this context the court considered that even if the physician's therapy could be negatively influenced when warning against a product that caused concerns in the consumer, it would not be justified to leave the consumer unaware of possible side-effects. The court pointed out that there might be possible exceptions to the general obligation of the manufacturer to give full disclosure to the consumer in the case of a prescription drug, provided that the physician will be fully informed about existing suspicion of side-effects and all the connected questions, so his control would be guaranteed. But as far as over-the-counter drugs are concerned, which can be taken without a physician's recommendation and control, the court expressed that the manufacturer cannot leave the consumer without the required information.

In conclusion the court explained that it cannot in general be conclusively established when exactly the pharmaceutical manufacturer has to become active after receiving knowledge of side-effects of his product. However, according to the nature of the situation there would be no general, valid set of requirements for each single case because different factors have to be taken into account. As such the court had regard to the following: the seriousness of the suspected health damage, whether the symptoms will ease off fast or slowly, or be indicated as therapy resistant or irreversible, as well as the frequency of their occurrence and, last but not least, the therapeutic importance of the drug.

Considering these factors, the risk apportionment to the debit of the manufacturer and the protective interests of the consumer, the pharmaceutical manufacturer always has to take steps when the consumer's protection calls for it. [135]

Which protective measures the pharmaceutical manufacturer has to take, if his product is suspected of having side-effects, depends according to the court conclusively on how the protection of the consumer can be realized most effectively. As measures worthy of consideration, which directly serve the consumer's protection, the court mentions essentially the following: a sufficient instruction of physicians and consumers, the introduction of a prescription requirement, and the product's withdrawal from the market. Which of these will be required in particular, will be dependent on the circumstances of

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[135] *LG* Aachen [1971] JZ 507 at 516.

each case and as mentioned before, it will be dependent on different criteria, such as seriousness, frequency and the prospects for recovery.

The court stresses that the giving of instructions to the consumer is absolutely necessary in the case of over-the-counter drugs, because in the absence of a physician's control the required consumer's protection and his right to make a decision as to whether he wants to take the drug or not, can only be guaranteed if he on his part is informed.[136]

The physician necessarily needs to be informed about possibly harmful dangers of a product, in the case of prescription drugs, to be able to perform his control function.[137] Also, he takes responsibility for the prescription of a drug, and he is also on his part obliged to give full disclosure to his patient.[138]

In addition, independently of any warnings given to the consumer, the physician also needs to be instructed about possible side-effects of over-the-counter drugs. Otherwise there would be the possibility that the patient might follow the instructions of his confidential physician disregarding warnings of the - for the patient - anonymous pharmaceutical manufacturer. Or he might follow the instructions of the manufacturer, ignoring his physician's advice, which would jeopardize the applied therapy.[139]

Following this, the court discussed requirements concerning the contents and form of an adequate instruction or warning. The court proceeded as follows: first the pharmaceutical

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[136] *LG* Aachen [1971] JZ 507 at 516.
[137] *LG* Aachen [1971] JZ 507 at 516 f.
[138] *LG* Aachen [1971] JZ 507 at 515.

manufacturer has to point out the risks involved in the product's use, in a way that is clear and unequivocal and understandable to lay-people, so that the physician and the consumer will be in a position where they can decide, if and for how long they want to risk the use of the drug. If indeed the manufacturer does not think it preferable actually to withdraw the product from the market, he has to provide another safe method for avoiding the damage. Finally the information needs to be free of misleading statements and additions which downplay the risks, because this would jeopardize their protective purpose.[140]

As far as the form of the instruction is concerned, the warning in the package insert is required to be made recognizable in some striking way. Moreover, it has to be made certain through a special package design; for instance by changing the color, or even better by an explicit notice or warning (*Hinweis*), so that any change in the package insert will be brought to one's attention. This is especially necessary if the drug in question is a long-term usage drug, because the especially endangered long-term drug users, according to experience, do not read the package insert again with every new purchase. In addition physicians, considering the large amount of drugs that are available, and are not able to follow each modification of a package insert, have to be informed by an unequivocally marked revised form of the basic prospectus of expert information; and also through one, or if necessary more, information notes (*Informationsschreiben*). These notes have to be clearly distinguishable from advertising brochures, folders or leaflets, because otherwise

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[139] *LG* Aachen [1971] JZ 507 at 517.
[140] *LG* Aachen [1971] JZ 507 at 517.

there would be a risk that they will be thrown out unnoticed. It is easy to imagine, for instance, an enclosed letter which would stand out by reason of its special color or a particular imprint, for example: "Important Information about Side-effects! Please Note!".[141]

2. Contents and scope of the warning

The case law available in the field of pharmaceutical product liability is notably smaller than in the area of other products. But there is case law, especially in regard to pharmaceutical products as well as in closely related fields such as food or pesticides, which has constantly further developed and improved the law of pharmaceutical product liability jurisprudence to favour the consumer's protection. These cases will be presented here in more detail than the numerous cases that deal more generally with the non-pharmaceutical manufacturer's duty to warn.

a. The *"Estil"* case[142]

The *"Estil"* case, decided by the Federal Supreme Court (*Bundesgerichtshof - BGH*), also deals with the pharmaceutical manufacturer's obligation to inform, it refers to an instruction defect.

It confirms at the highest court level the legal principle of the pharmaceutical manufacturer's duty to give instructions and to warn about his product, which had already

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[141] *LG* Aachen [1971] JZ 507 at 507, 517.
[142] *BGH* [1972] Neue Juristische Wochenschrift 2217 ff.: herafter cited as: NJW. Translation based on B. S. Markesinis, at 362 f.

been stated by the Provincial Court of Aachen in the *"Contergan"*-Thalidomide case. It also determines the contents and scope of this duty.

aa. Facts and substantive background

"Estil" was the name of an anesthetic being employed for short-term narcoses in hospitals as well as in general practice, which was to be administered intravenously only. On 12 October 1961 the plaintiff, a farmer's wife born in 1920, went to a hospital for minor gynecological surgery to be carried out by its director. In preparation for it, and to induce brief anesthesia, Dr. M, his assistant, injected "*Estil*", produced by the defendant, in the bend of the plaintiff's left arm. Accidentally the anesthetic was injected into an artery. This led to a serious disturbance of the plaintiff's circulation and necessitated, finally, the amputation of her upper arm.

Beginning in August 1960, *"Estil"* had been subject to clinical tests in several hospitals. Already during this period an accidental injection into a patient's artery had resulted in the amputation of the right arm. Despite this incident *"Estil"* was put on the market for sale on 1 April 1961, after it had been registered with the Senator for Health in Berlin. The package insert attached contained in its section for "contra-indications" the following sentence, pointed out in bold type: "Intra-arterial injection must be avoided with certainty." This same instruction was also given in the expert information for physicians. After the accident involving the plaintiff in this case, *i.e.*, after 12 October 1961, the warning attached to the package was augmented twice. It appears that it was only after 16 October 1961 - *i.e.*, after the incident involving the plaintiff - that the defendant recommended for the first time in the package inserts that injections be made in the lower

arm for preference, and that at first only ½ ccm. as an experimental dose be used; but even then the defendant had not mentioned the nature of the possible danger. This was done only in the third version, when called upon by the authorities, from January 1962 onwards. On 9 February 1962 the defendant withdrew *"Estil"* from sale, by which time a number of such accidents had occurred, most of them involving the loss of an arm. Such incidents totalled at least eighteen, of which nine had happened before the plaintiff's accident in this case. Besides that, in some cases of prolonged *"Estil"*-narcosis, kidneys suffered damage, in one case with fatal effect.

The plaintiff claimed damages from the defendant. The Court of First Instance rejected the claim, but the Court of Appeal allowed it. A second appeal by the defendant to the Federal Supreme Court was unsuccessful.

bb. The decision of the Federal Supreme Court (*Bundesgerichtshof*)

The Federal Supreme Court confirmed the decision of the Court of Appeal in holding the defendant to be liable in delict (§ 823 I *BGB*)[143], because he caused the loss of the plaintiff's arm by having culpably violated his public duty of care in his capacity as a pharmaceutical manufacturer. While the Court of Appeal reached this view primarily by finding that there had been a lack of sufficient clinical tests before *"Estil"* was put on the market, the Federal Supreme Court affirmed the Court of Appeal's findings on the ground

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[143] Observation: The manufacturer's liability in this case is only based on § 823 I *BGB*. Obviously that is, because the Pharmaceutical Products Act of 1961, which could have been considered as a protective law in the sense of § 823 II *BGB*, was not in force, when the events of this case occurred. In addition a reason might be the fact that the Pharmaceutical Products Act of 1961 did not provide regulations concerning the duty of the pharmaceutical manufacturer to disclose information about his products.

of insufficient information concerning the dangerous nature of the medicament.[144] In the court's opinion the defendant had violated its public duty of care, *i.e.*, the duty to inform, as a manufacturer of pharmaceutical products, by failing to indicate openly in the package insert and the medical prospectus the absolute arterial intolerance of *"Estil"*, which the manufacturer knew to be true.[145] The Courts held against the defendant, above all, that he was content to include a general warning in a notice included in the package and in the prospectus sent to physicians without having indicated in any way the serious, possibly irreparable, consequences of a misdirection of the injection into the artery, although he was well aware of them. In the Court's opinion, there was all the more reason to do so because, according to the unanimous opinion expressed in specialist medical circles, an accidental intra-arterial injection could not be avoided with certainty, especially if administered in the bend of the arm. The danger inherent in particular in the bend of the arm in this respect could not have escaped the attention of the research department of the defendant's enterprise, directed as it was by a medically qualified person.

Further the Federal Supreme Court agreed with the Court of Appeal that, if the defendant had, according to his duty, drawn the attention of every medical person to the existing risk in such a forcible manner from the beginning, or at least after a Congress of Anesthetists held on the 8 October 1961 where the *"Estil"* incidents were discussed, Dr. M. would have avoided the bend of the plaintiff's arm. And if he had approached the artery nevertheless, he would have noticed it at any rate while making an experimental preliminary injection. Thus the incident would have been avoided.

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[144] *BGH* [1972] NJW 2217 at 2218 ff.
[145] *BGH* [1972] NJW 2217 at 2219 f.

(1) The duty to warn: general principles

In the further course of this decision the *BGH* laid down the following principles: [146]

That it had been recognized for a long time by the practice of the courts that it is the duty of the manufacturer, the violation of which may render him liable to third parties for any ensuing damages, to give an effective warning of specific dangers emanating from a product brought on the market. Moreover the requirements are especially strict for providing information about possible dangers connected with pharmaceutical products. And further, that in the face of this principle any consideration of the manufacturer's interest in promoting sales is excluded.

Especially focusing on a situation where a medical practitioner is involved in the product application, as here, with an anesthetic, the *BGH* pointed out the manufacturer's obligation towards the physician as follows: The medical practitioner ought to be informed of the full extent of the risk in selecting the particular pharmaceutical product, because only in this way will he be warned particularly to use the utmost care and induced to abandon its use entirely in case of doubt.

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[146] *BGH* [1972] NJW 2217 at 2220 f.; It may be worthy of note: By laying down these principles, which are still valid until the present time, the *BGH* did not directly refer to the legal statements of the *LG* Aachen in the "*Contergan*"-Thalidomide case, concerning the pharmaceutical manufacturer's duty of care towards physicians and consumers. Instead the *BGH* made reference to an article of Hans Helmut Günter, *"Sorgfaltspflichten bei Neuentwicklung und Vertrieb pharmazeutischer Präparate"* [1972] Neue Juristische Wochenschrift 309 at 309 ff.: hereafter cited as NJW, which basically summarizes the principles found in the "*Contergan*"-Thalidomide decision.

Self-evidently, the manufacturer has a duty of care towards the public to fully inform physicians, who are supposed to use the product, of its specific danger and to warn them against it. Especially, if it is conceded that the continued marketing of a hazardous pharmaceutical product can still be justified having regard to its special advantages, it is necessary to acquaint the medical profession clearly and explicitly with any known grievous risks connected with usage of the product. Only thus will a medical practitioner be able correctly to balance the risk, which is involved to a greater or lesser degree in the use of every pharmaceutical product, against the benefit hoped for on the part of the patient in the individual case; and only thus can the practitioner, if necessary, give proper advice to the patient in making up his mind.[147]

The *BGH* assessed also: That the pharmaceutical manufacturer cannot be exonerated from this obligation by referring to alternative methods or practices[148], which might carry for other reasons an even higher risk or quota of incidents. The old medical maxim, primarily not to create more harm, militates against the acceptance *a priori* of a certain quota of incidents. Instead every recognizable source of danger - especially, however, one which is already well known - must be eliminated in dealings with patients, be they diagnostic, anesthetic or therapeutic, if and in so far as it can be reasonably avoided; this applies even if actual danger is only expected to materialize in relatively few instances.

Even under consideration of the fact that the duty to avoid danger is primarily incumbent upon the physician who, subject to agreement with the patient, determines the treatment,

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[147] *BGH* [1972] NJW 2217, 2220 f. - "*Estil*".

[148] In this case, *e.g.*, other anesthetic methods.

it would not correspond with the realities of modern pharmaceutical specialization to impose this duty upon him alone. Here the responsibility, and with it the manufacturer's duty of care, increases to the extent to which production of the pharmaceutical product is based on development which cannot be repeated easily or even be understood by the medical practitioner. It is also enlarged, above all, where the manufacturer himself, through intensive advertising among the medical profession, seeks and achieves influence over a choice in favour of his product and no other.[149]

Furthermore the *BGH* held that it can not be conceded to the pharmaceutical manufacturer that he can rely on publications in medical journals to provide the medical profession with information about his products. This reasoning reflects due consideration of the view-point that general medical practitioners, who were mainly concerned with using the product in this case, do not all read specialized publications regularly. Additionally, these publications might not properly be regarded as entirely unbiased and objective, insofar as they are supported and promoted according to an alleged custom by the manufacturers themselves. Therefore the reliance on available literature cannot be allowed as excusing a failure in the giving of usage instructions.[150]

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[149] *BGH* [1972] NJW 2217 at 2220.
[150] *BGH* [1972] NJW 2217 at 2221.

(2) Self-evident forms of misuse

Finally the *BGH* explained its opinion on the question, whether a drug manufacturer can only be held liable for the application of its product in accordance with its intended, appropriate and ordinary use. The *BGH* argued as follows:

This is only correct in so far as an intentional misapplication (*e.g.*, oral instead of external, as directed) is at issue. In such circumstances the occurrence of an unforeseen conduct may break the chain of causation. However, even to that extent the manufacturer is not exempt from giving appropriate warning, as the case may be, against likely, self-evident forms of misuse (*naheliegender Mißbrauch*), *e.g.*, by a clear notice "for external use". The duty to give notice is all the more important where it is necessary to prevent not an intentional but a negligent misapplication, if this possibility is not totally remote and is bound to have surprisingly severe consequences. The question as to whether the medical practitioner also acted negligently remains irrelevant as long as the manufacturer is to be blamed specifically for not having forestalled such mistakes of the medical attendant which are not beyond expectation. According to general opinion[151], the fact that another person has also caused the illegal act does not exonerate the tortfeasor either altogether or in part.[152]

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[151] In support of this opinion the court referred to § 840 I *BGB*, which provides: "If several persons are side by side responsible for the damage arising from a delict, they are liable, as joint debtors."
[152] *BGH* [1972] NJW 2217 at 2221.

cc. Summarizing results: The duty to warn after the *"Estil"* decision

The pharmaceutical manufacturer under delict law[153] thus has a duty to warn the consumer about possible dangers emanating from his pharmaceutical products. Regarding pharmaceutical products the requirements of disclosure, information and warning are especially strict. The required conditions that he has to meet in view of his duty can be summarized under the following headings:

(1). The addressee of the warning

Considering the *"Contergan"* and the *"Estil"* decisions in context, it is obvious that the main focus lies in the protection of consumers. This goal will be achieved best, if the patient is fully informed about any risk and dangerous consequences involved in taking a pharmaceutical product, so allowing him to make a deliberate decision whether to use a product or not. Because it is safe to assume that the informational superiority regarding his products will most likely be with the pharmaceutical manufacturer[154], in general, he is obligated to inform and warn both the patient-consumer, *e.g.*, in the package insert, as well as the medical practitioner, *e.g.*, in learned journals and other expert media.[155] This

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[153] Observation: It is important to realize, that the delict law requirements demanded for sufficient user instructions can be more extensive in the sense of stricter than those provided under the Pharmaceutical Products Act -*e.g.*, § 10, § 11, § 11a *AMG*; in other words: a package insert examined and approved by the federal health office can be insufficient according to delict law liability provisions, Hart in: Hart et al., at 151.

[154] *LG* Aachen [1971] 507 at 515.

[155] Karljosef Franz, "*Anmerkung* (commentary) *BGH* [1972] NJW at 2217 ff. - *"Estil"*" [1972] Neue Juristische Wochenschrift 2217 at 2218: hereafter cited as NJW; *LG* Aachen [1971] JZ 507 at 515 f. Recent case law jurisprudence of the Federal Supreme Court, considering instruction duties in product liability cases, even admits the last product seller who gives the product to the consumer into the group of possible addressees of instructions and warnings besides the ultimate consumer, *BGH* [1998] NJW at 2905; Hans

is based on the idea of providing the consumer with his own source of necessary information, but also the prescribing physician who, in fulfillment with his own duty to give full disclosure to his patient, can only pass on what he was informed about. Depending on the situation, however, the duty towards one or the other addressee might be invested with more importance. For example in regard to "over the counter drugs", which can be used without an experts' advice, control and supervision, especially the instruction and warning of the patient and consumer is necessarily of paramount concern[156], whereas in relation to other products, such as vaccines or the local anesthetic *Estil*, which are never actually sold to the patient and consumer directly but used and applied by the physician only, more emphasis is put on the requirement that the physician be informed, instructed and warned. This is because the concept follows the ideal assumption, that the physician would pass the necessary information on to his patient.

Consequently, the circumstances of each case determine how the pharmaceutical manufacturer will best and most adequately arrange to meet his obligation, to impart the necessary information about the risks and dangerous consequences involved for the consumer in using his product.

Josef Kullmann, "*Die Rechtsprechung des BGH zum Produkthaftpflichtrecht in den Jahren 1997/ 1998*" [1999] Neue Juristische Wochenschrift 96 at 98.

[156] *LG* Aachen [1971] 507 at 516.

(2). Formal requirements

Thus far, the Federal Supreme Court has basically confined the formal conditions for a warning to the summarizing term "clear"[157], *e.g.*, by a clear labelling "for external use only".[158] A more detailed, objectively justiciable, or concrete, term was not available up to that time.[159] However, commentaries in the legal periodicals on the occasion of this decision also insist that instructions and warnings have to be attached to the product itself, if necessary[160], because the manufacturer cannot rely on the product user (here the medical practitioner) actually taking notice of the expert publications in time. It also might be necessary to place the warning directly on the drug container if, in cases of products designed for repeated use, it has to be expected that it will be applied by different users. After all, the manufacturer cannot assume that the package insert will always be given along with the product.[161]

(3). Material or substantive requirements

Regarding contents or substance, the Federal Supreme Court demands that instructions, by giving clear designation of specific dangers, must unequivocally and obviously inform the consumer of the full extent of the known risks involved in using the particular

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[157] BHG [1972] NJW 2217 at 2221; this general observation was still even expressed by Friedrich Graf von Westphalen, *"Instruktionspflichten des Warenherstellers im Lebensmittelbereich - Zum "Baby-Bottle-Syndrom""*, [1994] Betriebs-Berater (Beilage 18) 1 at 3: hereafter cited as BB.
[158] BHG [1972] NJW 2217 at 2221.
[159] Similar critical observation by Graf von Westphalen, [1994] BB (Beilage 18) at 4.
[160] The same had already been decided in the *"Fußboden-Klebemittel"* ("floor covering adhesive") decision of the *BGH* [1960] VersR 842 at 843.
[161] Schmidt-Salzer, "*Anmerkung* (commentary): *BGH* [1972] NJW 2217 ff. - "*Estil*"" [1972] Neue Juristische Wochenschrift 2219 at 2219: herafter cited as NJW.

product, including any imminent extraordinary consequences.[162] This means according to scholarly opinion, that instructions must be clear, sufficient, complete and appropriately detailed (*substantiiert*). In this connection it was suggested that it might not be enough only to refer to the danger. If necessary the instructions have to inform how the product can be used without dangers and to specify what kinds of preventative measures need to be taken and which modes of use have to be avoided[163]. All this applies regardless of how many people are expected to be negatively affected by using the product, if human bodily integrity or health is at risk, *i.e.*, even if reactions have to be expected only in a few sensitive people.[164]

In this context the Court made clear that in case of a neglected warning the manufacturer cannot be exonerated by relying on publications in expert journals because general experience shows that physicians do not always read them.

Finally it was pointed out that the pharmaceutical manufacturer's material obligations even include the duty to warn adequately about self-evident forms of misuse.

b. Self-evident forms of misuse such as excessive use, overdose: the *"asthma spray"* case

Following the course of extending the pharmaceutical manufacturer's duty to warn even about dangers arising out of self-evident forms of misuse, as determined in the "*Estil*" decision, the Federal Supreme Court has had another opportunity to discuss this issue in detail, in a further decision involving a pharmaceutical product.

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[162] *BGH* [1972] NJW 2217 at 2220 f.
[163] Schmidt-Salzer, [1972] NJW 2219 at 2219.

aa. The facts

Throughout his many years of chronic illness, a 24-year-old asthma patient had regularly been using the defendant-manufacturer's asthma spray *"Alupent Dosier-Aerosol"* to ease his breathing. The package insert contained user-information that roughly speaking instructed the patient in case of a threatening or acute asthma-attack first to use only one aerosol puff; but it allowed in particularly serious situations a second and third puff, always after a five minute break. The patient was advised to leave at least two hours between the next inhalation of another one to three puffs. During his last asthma-attack the patient used the product often because he could not feel any relief. The exact amount is not known. It might have been fifty or more at intervals of a few seconds. He died in the course of this attack.

bb. The Court's decision

On the occasion of the plaintiff's appeal the Federal Supreme Court held that the damage claim of the surviving dependents was in principle justified under the provisions of § 823 I *BGB*,[165] for the manufacturer's breach of his duty of care. The Court confirmed or repeated the *"Estil"*- decision, reasoning that in the framework of his delict law obligation to warn the consumer about possible dangers emanating from his products, the

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[164] Kullmann in: Kullmann/ Pfister, Kza. 1520 at 37.

[165] With the *"asthma spray"* decision the Federal Supreme Court for the first time comprehensively and in detail commented on pharmaceutical product liability in virtue of the Pharmaceutical Products Act, here in particular: § 84 S. 1 *i.V.m.*(in connection with) S. 2 Nr. 2 *AMG*, Erwin Deutsch, *"Anmerkung zu* (commentary on): 106 *BGHZ* 273 ff. - *"Alupent Dosier-Aerosol"* (*"asthma spray"*)" [1989] Juristenzeitung

pharmaceutical manufacturer is also obligated to warn about the limits of the product's use and the dangers arising out of self-evident forms of misuse, which do not lie wholly outside of the product's intended purpose.[166] This extended duty to warn is of great importance in the field of pharmaceutical products.[167] According to the Court's findings the pharmaceutical manufacturer has to call the patient's attention to risks of a clear and manifest over-dosage. Here the Court held that the user instruction was insufficient and therefore defective, because it did not indicate the allowed maximum daily dosage and did not stress strongly enough the serious health risks arising out of a large overdose.

Concerning the pharmaceutical manufacturer's extended duty to warn, the Court reasoned as follows:[168] In cases where serious dangers to body and life are likely to occur, caused by too high a dosage or - as in the case of an aerosol - caused by too frequent use in the course of only a single attack, the pharmaceutical manufacturer does not meet the required obligations concerning user-information in correspondence with the knowledge of medical science, if he only includes the basic details required of any pharmaceutical product. In this case the user-information must rather contain also an indication about maximum daily dosage and, circumstances requiring, additionally a warning, if on the grounds of research or other reliable data, health injuries to consumers have to be feared in the absence of timely warning. The pharmaceutical manufacturer has to include all warnings that are necessary. This includes also the required reference to dangers arising out of the drug's application, above all warnings of dangers known to medicine and

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855 at 855: hereafter cited as *JZ*. In the further course of its reasoning though, the Court also reflected upon the claims on the grounds of § 823 I *BGB*.

[166] 106 *BGHZ* 273 at 283 - *"asthma spray"*.

[167] Hart in: Hart et al., at 152.

arising from immediate not far fetched, extraordinary and improper use incompatible with the intended purpose (*bestimmungswidriger Fehlgebrauch*) of the ordinarily harmless drug, *e.g.*, warnings as to the application depending on the product's nature and consequences of improper use (*Anwendungs- und Folgenwarnung*). This is of particular importance in the case of risks arising out of improper use of pharmaceutical products, because application mistakes are the most frequent cause of pharmaceutical injuries. It is the pharmaceutical manufacturer's unalterable obligation to obtain all necessary and relevant information about the meaning and nature of pharmaceuticals, their limits and dangers attending their application, and to convey this in appropriate form to the consumer, in light of the latest findings in medical science. Risks that are likely to arise out of improper use and over-doses of drugs have always to be pointed out by the pharmaceutical manufacturer, if and insofar as it cannot be expected that these risks are already known to each patient. This duty is not in any case limited to dangers that occur from accidentally improper use or from carelessness resulting in an overdose. Rather it extends to any improper use which the pharmaceutical manufacturer should reasonably anticipate. That said, it has to be admitted that where pharmaceuticals are concerned there is no obligation in general to warn about dangers occurring from excessive use or misuse, that has to be considered as unreasonable. However, in the context of pharmaceutical products that are intended - such as "*Alupent Dosier-Aerosol*" in asthma attacks - to be applied by the patient even in dramatic situations, warnings against possible life-threatening dangers arising from excessive use are also required. In the case of drug use

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[168] 106 *BGHZ* 273 at 278 ff., - *"asthma spray"*

during an attack, the patient is in general powerfully motivated by the urge to release himself from anxieties of such an attack as soon as possible. Additionally it has to be taken into consideration that in the case of a medium of presentation such as a spray, the threshold of inhibition in such situations of exigency is noticeably lower in comparison to taking tablets or capsules. As the patient for these reasons will tend to put aside fears about any dangers of the pharmaceutical product and its over-use, they have to be impressed upon him at least through a user-information insert, if not indeed through labelling on the package. To this end, it would have been enough in this case to warn clearly that to exceed the directed dose could present significant dangers for the patient.

In conclusion the Court stated that the manufacturer is not automatically exonerated from his delict law duty to warn, if certain research results about danger or health damages do not yet exist at the time of distribution, because according to the findings in the *"Contergan"*-Thalidomide decision, the manufacturer is, at least when people's health or bodily integrity is threatened by his product, already obliged to give warnings, when on the grounds of reasonable and probable, though not necessarily overwhelming, suspicion there is reason to fear that health injuries could arise.[169]

Finally, the pharmaceutical manufacturer's duty to warn about obviously foreseeable, self-evident forms of misuse - as described above - might arise out of different areas of his responsibility. On the one hand such a duty arises out of the responsibility to instruct and warn the consumer, if on the grounds of actual knowledge, experience or research

results he has reason to suspect his product being dangerous in reasonably foreseeable ways of usage at the time of distribution. On the other hand this duty might materialize also in light of subsequently received knowledge following his obligation of constantly monitoring his distributed products, regarding their dangerous effects resulting from certain ways of application. That would be so even if there was no such reason for suspicion in the beginning, but such reason revealed itself later.[170] In the latter case the duty to warn is a reactive obligation resulting from the obligation to take danger-averting measures, if the observation or monitoring of the product reveals certain safety risks.[171]

c. Limits of the duty to warn

aa. The *"sniffing"* case

The Federal Supreme Court has also had the opportunity to define limits for instruction and warning duties under delict law in the field of product liability.

In the so-called "sniffing" case[172], the Federal Supreme Court had to decide if the manufacturer of a cryogen, which was also used for the purpose of cleaning refrigerating machines, was obligated to warn the user about dangers arising out of intentional misuse of the product as a medium for intoxication. The occasion was the death of a 15-year-old boy who had been working in his father's business and inhaled the vapours of the cryogen, which he had first poured into a glass. Although this case lies outside the direct

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[169] 106 *BGHZ* 273 at 283- *"asthma spray"*; *LG* Aachen [1971] JZ 507 at 515 f. - *"Contergan"*; Günter, [1972] NJW 309 at 312; 80 *BGHZ* 186 at 192 - "apple-scab I".

[170] Hart in: Hart et al., at 152.

[171] Kullmann, [1997] NJW at 1749 f., referring to 163 Entscheidungen des Reichsgerichts in Zivilsachen 21 at 26: hereafter cited as *RGZ*.

scope of pharmaceutical products, it illustrates the bounds of misuse where the manufacturer's duty to warn is concerned. We can in this way proceed on the assumption that these principles also apply in cases of pharmaceutical products.

The Court held that generally the manufacturer's obligation to give instruction and warning in regard to product dangers only exists in relation to the ordinary use of the product as broadly construed.[173] Even though the Court had considered in this connection in the *"Estil"* case, that this duty might also in special circumstances include the duty to warn about obviously self-evident forms of misuse, and had further reflected upon such an "improper" use as "oral instead of external use", or intra-arterial instead of intra-venous application, such abuses had still been within the framework of the intended purpose of the product use, *i.e.*, as a medicine. But it is exactly the duties of specific instruction and warning about a product that must, as the Federal Supreme Court pointed out, come to an end as a rule, where the use of the potentially harmful product, has nothing to do with the intended product's purpose at all.[174] This is because the manufacturer's obligation to warn is only aimed at the intended purpose of the product. In other words, the warning requirements reach only so far as the bounds of the product's generally expectable and intended use.[175] The manufacturer does not have to consider usage that is intentionally contrary to or incompatible with its intended purpose (*vorsätzlich bestimmungswidriger Gebrauch*).

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[172] *BGH* [1981] NJW 2514 at 2514 ff.
[173] *BGH* [1987] VersR 102 at 103 - "*Verzinkungsspray*", where the Federal Supreme Court pointed out that the cause of dangers also depends on the manner in which the product will be normally used.
[174] *BGH* NJW 1981, 2514 at 2515.
[175] Confirmed by 116 *BGHZ* 60 at 65 - "children's tea I".

bb. The "apple scab" case I (*"Apfelschorf"*-Fall I -*'Derosal'*)

In the "apple scab" case, the Federal Supreme Court had to consider the warning issue in connection with a pesticide which had lost its efficacy against fungus developing on apple trees. The Court marked two absolute limits in regard to the manufacturer's obligation. These observations are of general importance and therefore valid for all products including the distribution of pharmaceutical products.[176] The Court marked out the framework in which the manufacturer's duty to warn can arise. According to the Court's opinion the manufacturer is not allowed to stand idly by until seriously damaging events have occurred, before taking countermeasures. A danger does not have to have manifested itself in fact in order to generate duties of defensive reaction. On the other hand not every remotely existing possibility of danger gives rise to duties of care and duties to warn.[177] It is indeed a challenging issue to decide when the duty to warn sets in. This moment, as well as the contents and scope of a warning, are essentially determined by the respective interests at risk and are above all dependent on the dimension or degree of peril.[178] Therefore the decision clarified two further principles: referring to the well known pronouncements of the *"Contergan"*-Thalidomide case, the Court confirmed that the manufacturer, at least when people's health or bodily integrity is threatened by his product, is already obliged to give warnings, when on the grounds of a reasonable and

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[176] Hans Josef Kullmann, "*Die Bedeutung der "Apfelschorf"-Urteile des Bundesgerichtshofes für die Pharma-Industrie*" [1982] PharmaRecht 6 at 7.
[177] 80 *BGHZ* 186 at 191 - "apple scab I".
[178] 80 *BGHZ* 186 at 191 f.

probable, though not necessarily overwhelming, suspicion, there is reason to fear that health injuries could arise.[179]

In contrast to that, the Court referred to property damage to illustrate the distinctions governing the determination of the exact moment for a warning requirement as follows: if there are only proprietary damages to be feared, the requirements both of timing and scope of warning are not equally as strict. In this case it might be allowable, that the manufacturer, before giving a warning, confine his efforts to further examination in laboratories, testing plants, etc. and to intensive monitoring regarding his product's efficiency in practice. This would be so, even if the danger has already "intensified", but where it is still open to doubt, whether and under what circumstances it will become acute. That is so, at least when it can reasonably be expected that he will still be able to take sufficient counter measures early enough.[180]

d. Ineffectiveness or inefficacy of products: "apple scab" cases

In the "Apple scab" cases the Federal Supreme Court had to address the further question, beyond when, if or indeed whether a manufacturer of plant-protective agents has a duty to warn the consumer about ineffectiveness (*Unwirksamkeit*) or inefficacy (*Wirkungslosigkeit*) of his product. In these cases[181] farmers had claimed compensation

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[179] 80 *BGHZ* 186 at 192, original *LG* Aachen [1971] *JZ* 507 at 515 f. - "*Contergan*"
[180] 80 *BGHZ* 186 at 192.
[181] The Federal Supreme Court actually decided four "apple-scab" cases on 17th March 1981, but only two were published, one of which was the "apple-scab I" decision referring to the fungicide/pesticide *"Derosal"*, 80 *BGHZ* 186 ff., the other one was the "apple-scab II" decision referring to the fungicide/pesticide *"Benomyl"*, 80 *BGHZ* 199 ff. Both of these decisions deal with the question whether a manufacturer has in general a duty to warn the consumer about the ineffectiveness or inefficacy of his

from the manufacturers of so-called systemic fungicides made to fight the apple scab fungus. Under the provision of § 84 S. 2 Nr. 1 *AMG*[182] the pharmaceutical manufacturer was not liable if his product was ineffective (*unwirksam*).[183] Nevertheless, something might be done to establish liability by recourse to § 84 S. 2 Nr. 2 *AMG*, as it serves a different area of protection.[184] In combination with regulations about labelling (§ 10 *AMG*), package inserts (§ 11 *AMG*) and expert information (§ 11a *AMG*), the requirements provided by § 84 S. 2 Nr. 2 *AMG* can also be met if a pharmaceutical product under correct ordinary use is not effective and the user dies or suffers severe pain or further health damage as a result of, *e.g.*, a dosage instruction, that was indicated too low or did not refer to likely interaction with other products that resulted in such ineffectiveness. However, as mentioned above, the Pharmaceutical Products Act does not provide a complete system or comprehensive scheme of liability regulation concerning pharmaceutical manufacturers. The special liability regulation § 84 *AMG* is only a further ground for liability over and above the general delict law liability provided by § 823 *BGB*, because both liability systems compete side-by-side with each other as concurrent claims. The *"Apple scab"* decisions dealt with the conditions of liability under § 823 I *BGB* if a product was ineffective. Therefore the principles found in that decision are also

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product. However they put emphasis on slightly different issues, such as the duty to warn ("apple scab I '*Derosal*'") and the duty constantly to monitor the effectiveness or efficacy of a product once it has been put on the market ("apple scab II '*Benomyl*'").

[182] § 84 S. 2 Nr. 1 *AMG* only provides for liability, as it will be explained later, if the pharmaceutical product under correct ordinary use has harmful effects. Only unwanted side-effects are so considered (§ 4 XIII *AMG*), but not the failure to achieve the expected successful treatment.

[183] Hans Josef Kullmann, "*Haftung des Pharmazeutischen Unternehmers für nicht wirksame Arzneimittel*" [1983] PharmaRecht 196 at 200; Erwin Deutsch, "*Das Arzneimittelrecht im Haftungssystem*" [1979] Versicherungsrecht 685 at 686: hereafter cited as VersR.

[184] § 84 S. 2 Nr. 2 *AMG* allows damages claimed, if the harm has occurred as a result of labelling, expert information or instruction for use not complying with the knowledge available in medical science.

important for the pharmaceutical manufacturer's liability for ineffective drugs.[185] Furthermore the decisions also contain general explanations of liability under delict law which are important for the pharmaceutical manufacturer's liability, if his product has dangerous side-effects and the injured person happens to claim compensation which exceeds the pecuniary damage limits of the Pharmaceutical Products Act,[186] or claims non-material damages which are not provided under the Pharmaceutical Products Act.

It is actually quite difficult to hold a manufacturer liable at all under § 823 I *BGB* for ineffective products. However, this is of special interest here, in relation to the duty to warn. It is open to debate whether an ineffective product could as a matter of logic possibly have caused the damage, or indeed prior to that the danger of which the manufacturer would have been obliged to warn. One of the courts on the lower level questioned, for example, whether § 823 I *BGB* would at all establish a general duty to protect the interests of the consumer from dangers not arising from the manufacturer's own conduct, but from external agencies.[187] Take for example the dangers that materialized in the "*apple scab*" cases. These did not have their origin in the manufacturer's conduct but rather in the domain of the farmers, because the dangerous fungus that developed the apple scab already existed in the farmers' apple trees. Obviously the court answered in the negative concerning the manufacturer's legal duty to avert dangers, following from the protective purpose of § 823 I *BGB*, in cases where the

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[185] Kullmann, [1982] PharmaRecht 6 at 6: the heading of his article is called in translation " *The significance of the "apple scab" decisions of the Federal Supreme Court for the pharmaceutical industry*"; Kullmann, [1983] PharmaRecht 196 at 200.

[186] § 88 I Nr. 1 *AMG*: a limit of 1 million Deutschmarks, if a person is injured or killed.

primary cause for the damage caused had its origin in the sphere of the injured party and where the damage would not be prevented by reason of the inefficacy or inefficiency (*Wirkungslosigkeit*) of a product manufactured by the defendant.

The Federal Supreme Court did not agree. In the Court's opinion liability under the provisions of § 823 I *BGB* is not imposed at the outset, because the products did not cause the scab to happen. But it is imposed on the ground that it turned out to be ineffective to fight or avert the damaging fungus. In this connection the Court certainly admitted that the consumer's or user's interest in availing himself of the product's suitability for its intended use (*Gebrauchstauglichkeit*) itself must be basically reserved to the law of contracts, whereas delict law liability mainly serves the purpose of protecting the safety interests of the consumer for things already in his possession. Therefore disappointed expectations referring only to the defective product itself will be compensated solely through contract law, by way of warranties or guarantees. However, if the intended purpose for using the product consists exclusively in protecting the interests listed in § 823 I *BGB*, as explicitly mentioned by the Federal Supreme Court regarding property or indeed life and health, then also the use expectations, created by the manufacturer by putting his product on the market, might be secured for the sake of the particular interest according to general delict law principles, of course bounded by the limits of reasonable possibilities and expectations. In such cases the manufacturer is always then obligated to meet the security expectations of the user and to make sure that the product user does not

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[187] See Kullmann, [1982] PharmaRecht 6 at 6, referring to the decision made by the *LG Hamburg* in this case.

suffer disadvantages, if in view of those expectations he deters the consumer from using other more effective competing products or from taking any other measures to protect the endangered interest.

This jurisprudence also applies to pharmaceutical products[188], designed to prevent the outbreak or aggravation of sicknesses,[189] for example vaccines and even contraceptives[190]. However, the ineffectiveness of the product alone is not enough to make the manufacturer liable. A patient who has not found the desired protection by using a pharmaceutical product is not eligible for compensation, if the natural course of his sickness could have not been arrested by any other available means. But if another medication exists, which would have prevented the outbreak or exacerbation of a sickness or the development of pregnancy, there is a possibility for the pharmaceutical manufacturer to be held liable. A regular pre-condition to liability under § 823 I *BGB* is therefore that the person concerned would have been able to prevent the damaging course of events otherwise, and that this was left undone as a result of the manufacturer's conduct, which induced him to rely on the fitness of the particular product for its intended purpose.[191] It is then irrelevant to consider on which grounds the ineffectiveness was based. Examples would be that the drug did not have any therapeutic utility or effect, if its efficacy was time-limited but no expiry date made reference to this; if the sickness-

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[188] Kullmann, [1983] Pharma Recht 196 at 196; Erwin Deutsch, "*Arzneimittelschaden: Gefährdungshaftung, Verschuldenshaftung, Staatshaftung*" in: *Festschrift für Karl Larenz*, ed. by Claus-Wilhelm Canaris & Uwe Diederichsen (München: C.H. Beck'sche Verlagsbuchhandlung 1983) 111 at 115, 118.

[189] 80 *BGHZ* 186 at 189 - "apple scab I"; Deutsch, [1979] VersR 685 at 686.

[190] The Federal Supreme Court, for example, considers a pregnancy against the woman's will as actual bodily harm: *BGH* [1980] VersR 558 at 559.

causing germ or virus has developed a resistance against the product in the meantime; or, if the cause was a deficient instruction about possible interactions with other food or drug products that might result in inefficacy.[192] Anyway, the conditions were met in the present case, because farmers could have prevented the damage caused by the apple scab by using another product, to which the fungus was not resistant, or could at least have used it in alternation with the manufacturers' products, if the defendant manufacturers had only instructed them accordingly.[193] It was not in this instance decided whether the consumer's disappointed expectations would probably also trigger damage claims, if a product was not able to remove already occurred damage or to cure the sickness, *e.g.*, a painkiller that does not relieve the pain or an intended blood pressure lowering product does not fulfil its purpose.[194] But as the Court explicitly emphasized, the grounds of such a delict law liability are the general public's use and safety expectations inspired by the product, concerning the integrity protection of their interest when exposed to the product. As a matter of fact such liability can never arise, if the manufacturer refers on packages or package inserts to the information that a certain failure percentage has to be expected in using the product, as for example with contraceptives, and then this risk materializes later.[195]

In conclusion and by way of clarification, the pharmaceutical manufacturer's liability for ineffective drugs can be considered as within the context and scope of this thesis under

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[191] 80 *BGHZ* 186 at 190; Kullmann, [1981]WM 1322 at 1323.
[192] Kullmann, [1983] Pharma Recht 196 at 198.
[193] 80 *BGHZ* 186 at 190.
[194] Kullmann, [1982] PharmaRecht 6 at 6, Kullmann [1983] PharmaRecht 196 at 196.
[195] Kullmann, [1981] WM 1322 at 1323.

the issue of his responsibility to instruct and warn the consumer accordingly, if on the grounds of actual knowledge, experience or research results the manufacturer has reason to suspect that his product may be ineffective at the time of distribution. On the other hand, the manufacturer also has a reactive duty to warn under his obligation of constantly monitoring his distributed products with regard to their inefficacy, even if there was no such reason for suspicion at the time when he first put his product on the market.

e. Monitoring duty, duty continuously to observe the product and duty to warn as a reactive obligation; "apple-scab" case II (*'Benomyl'*)

The product monitoring or observing duty, and corresponding reactive duties, are also important manufacturers' duties, in the field of product liability. They also apply in the field of pharmaceutical product liability concerning the safety of a drug's use.[196]

In this context we have to look at the "apple-scab" cases again, as these have confirmed the establishment of the manufacturers' duty in the area of product monitoring and reactive duties. The monitoring duty is also a *"Verkehrssicherungspflicht"*[197] (duty of care) concerning product manufacturing, which comes into play in relation to the manufacturers' duty to warn, because the duty to warn can arise as a consequential duty, *i.e.*, as one possible reaction to the monitoring duty. This therefore influences its contents

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[196] Hart in: Hart et al., at 153 f.

[197] 80 *BGHZ* 199 at 202, "apple-scab II"-; Hans Josef Kullmann, "*Die Rechtsprechung des BGH zum Produkthaftungspflichtrecht in den Jahren 1994 - 1996*" [1996] Neue Juristische Wochenschrift 18 at 21: hereafter cited as NJW.

and scope, if the product observation reveals risks in a product's usage relating to dangerous side-effects of pharmaceutical products.

aa. The duty of monitoring the product

It has been recognized for a long time that the manufacturer's duties to ensure safety do not end with release of the product for distribution.[198] The "*Reichsgericht*"[199] had already decided that the manufacturer who becomes aware of possible dangerous effects of his products after distribution is obliged to do everything that can reasonably be expected from him, in the circumstances of the particular case, to avert them.[200] In the "apple-scab" decision II, *"Benomyl"*, the Federal Supreme Court fully and explicitly commented upon this problem and explained that it could not be left just as the *"Reichsgericht"* had left it. According to the Federal Supreme Court the manufacturer must not rely on receiving knowledge about such dangers more or less by chance. Rather he is obligated to put in place the necessary measures to get informed about the practical proof of efficiency or of satisfactory everyday use of his product[201]. This duty not only exists under contract law, but also under delict law, because the requirements in this context could not sensibly be of any lower standard. Therefore the manufacturer would also be obligated to the public, especially concerning mass produced and mass distributed products, to observe that these products may have as yet unknown harmful attributes and characteristics. He must also

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[198] Friedrich Graf von Westphalen, "*Neue Gesichtspunkte für die Produzentenhaftung*" [1971] Betriebs-Berater 152 at 156; Kullmann, [1981] WM 1322 at 1324.
[199] *RG* (Supreme Court of the German Reich).
[200] 163 *RGZ* 21 at 26; RG [1940] DR 1293 at 1293.
[201] Referring to *BGH* [1970] BB 1414 at 1415.

inform himself about other dangerous situations created by related consequences of his product's use.[202] The Federal Supreme Court was referring to all products that are mechanically manufactured in large amounts. This of course also includes most pharmaceutical products.[203] In this case the manufacturer has to act in conformity with, and continuously follow, the ongoing developments in science and technology in the relevant field. According to the Federal Supreme Court's final remarks on this issue, this includes, for companies distributing their products all over the world, the pursuance of results brought to light during scientific congresses and expert colloquia, as well as analyses of the entire expert literature.[204]

By way of conclusion, the following annotations or addenda have to be made in the context of the regulations of the Pharmaceutical Products Act. [205]

According to § 29 *AMG* the pharmaceutical entrepreneur in the framework of the pharmaceutical post marketing control (*Nachmarktkontrolle*) is obliged to notify the competent federal higher authority forthwith of any changes occurring in the particular documents submitted pursuant to §§ 22 to 24 *AMG* for receiving marketing authorization for his product. Furthermore he has immediately to report any case of suspected side-effect or interaction with other products that can be detrimental to health, which have become known to him, as well as giving notification of any frequent or serious abuse observed in an individual case, if this can directly or indirectly jeopardize human health,

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[202] 80 *BGHZ* 199 at 202 and now established case law, 99 *BGHZ* 167 at 171 ff. - "*Honda*".
[203] Kullmann, [1982] PharmaRecht 6 at 8.
[204] 80 *BGHZ* 199 at 203 - "apple scab II"; Kullmann in: Kullmann/ Pfister, Kza. 1520 at 51; Kullmann [1981] WM 1322 at 1325.
[205] See analysis by Hart in: Hart et al., at 153 f.

unless the information is unnecessary in light of further provisions or exceptions. In this regard the product monitoring duty is the first step triggering liability law (*haftungsrechtliche Vorstufe*). This means the product monitoring duty arising out of delict law is at the same time the civil law based liability condition arising out of the administrative or public law concept establishing a duty to notify. Due to the risk to the most important interests- those in life, health and body -, the high possible scope of damage, the possible multitude of injured people and the immense public interest in protecting the public from safety-risks posed by pharmaceuticals, or in preserving the safety of pharmaceuticals, delict law imposes high demands on the manufacturer by strict, comprehensive product monitoring-duties. The implementation of this obligation requires corresponding mechanisms to furnish and assess the necessary information. The liability law obligation following the product monitoring duty partially runs parallel with legal pharmaceutical organizational duties, such as to appoint a commissioner for the graduated plan according to § 63 a *AMG*, who is responsible for collection, assessment of emerging pharmaceutical product risks as they are notified, and for coordination of necessary measures. In this context an important role is also played by the experts referred to in §§ 75 and 76 *AMG* as risk announcer or adviser. Insofar as the Pharmaceutical Products Act provides legal provisions (*Vorgaben*, in the sense of legal requirements) regarding the business organization, this makes it easier to meet the liability law's organization duties following the product monitoring duty. The product monitoring duty though does not mean only the collection of risks of which knowledge has arisen elsewhere, but that independent product monitoring has to be organized by the manufacturer. This includes, besides the examination of patients', pharmacists' and physicians' information, the

inspection of the relevant national and international expert literature and corresponding expert *colloquia*, as well as the inclusion of information about clinical experiments into liability law; post-marketing control.

bb. The duty to warn as a reaction of the monitoring duty

The manufacturer who learns about product related security deficits by active or passive product monitoring is obligated to react appropriately and promptly,[206] if necessary, *i.e.*, to take the necessary danger averting measures[207] which can reasonably be expected.[208] Reactive duties, as a consequence of evident development defects through product monitoring, arise as soon as there is reason to suspect unjustifiable, unwanted pharmaceutical effects. In this case the manufacturer has the obligation, sounding in legal liability, to take security precautions, depending on the situation and circumstances of the particular case, either through warnings (*i.e.*, his secondary instruction duty)[209], restriction of indication, or recalling the pharmaceutical product from the market.[210]

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[206] Kullmann, [1996] NJW 18 at 21 referring to *BGH* [1994] NJW at 3349 ff. - "*Atemüberwachungsgerät*" ("oxygen control apparatus/ respirator").
[207] This obligation has long been recognized by litigation: 163 *RGZ* 21 at 26.
[208] Kullmann, [1996] NJW 18 at 21 referring to *BGH* [1994] NJW at 3349 ff. -"oxygen control apparatus/ respirator".
[209] 80 *BGHZ* 199 at 203 ff. - "apple scab II", where the defendant was found not to have objectively breached his reactive duty to warn, as the progressive ineffectiveness of the fungicide caused by the developed resistance of the fungus was neither known nor obviously foreseeable or predictable at the time of distribution.
[210] Hart in: Hart et al., at 154.

f. Extended aspects concerning responsibilities of manufacturers: children's tea or "Baby-Bottle-Syndrome" cases (*"Kindertee" -Fälle*)

The most recent decisions of the Federal Supreme Court dealing fundamentally with the instruction duties of manufacturers, including their duties to warn and to observe their products or their monitoring duty under the provision of § 823 *BGB*, concern cases that are in Anglo-American jurisprudence known under the term "Baby-Bottle-Syndrome"[211]. The first case decided by the Federal Supreme Court in Germany in 1991 is known as the *"Milupa"* case[212], named after the name of the company - *Milupa AG* - manufacturing carbohydrate or "sugar"-containing instant tea for children.[213] Some of these products had since 1982 been licensed as pharmaceutical teas as well.[214] The cases decided later, in 1994[215] and 1995[216], were more generally called children's tea (*"Kindertee"*) cases[217], obviously because defendant-manufacturers[218] other than the *Milupa AG* company were also involved.

aa. Facts

The factual background concerns the severe damage to children's milk-teeth, followed by tooth-decay and gum-infection or even damage to the mature or permanent teeth, caused

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[211] 116 *BGHZ* 60 at 66 - "children's tea I" (also called "*Milupa*" case).
[212] 12 November 1991, 116 *BGHZ* at 60 ff. = *BGH* NJW 1992, 560 ff.; see also *OLG* Frankfurt, (second instance) appeal decision from 11 December 1990, in: Axel Sander, *Arzneimittelrecht, Entscheidungssammlung zum Arzneimittelrecht* (Köln: Verlag W. Kohlhammer, 14. Lieferung Juni/1996) § 84 *AMG* case Nr. 5: hereafter cited as Sander; and *OLG* Frankfurt, another appeal decision from 18 March 1993, Sander, § 84 *AMG* case Nr. 5 b.
[213] Graf von Westphalen, [1994] BB (Beilage 18) 1 at 2.
[214] See facts of *BGH* [1995] NJW 1286 at 1286 - "children's tea III".
[215] 11 January 1994, *BGH* [1994] VersR 439 ff. - "children's tea II".
[216] 31 January 1995, *BGH* [1995] NJW 1286 ff. - "children's tea III".
[217] *BGH* [1995] NJW 1286 at 1287; Graf von Westphalen, [1994] BB (Beilage 18) 1 at 3.

by cavity-causing bacteria after long-term consumption of carbohydrate based children's teas. Such damage is caused by continuously sucking out of specially developed nursing bottles, whose modern orthodontic shaped mouthpieces (orthodontic nipples) would direct the thin liquid stream directly behind the upper front teeth. In all cases the plaintiffs had claimed to have continuously consumed the instant children teas and sometimes additionally other "sugar"-containing fruit or vegetable juices out of the bottles. Some of these bottles were also distributed by the tea manufacturing companies, for soothing children to sleep during the day and in wakeful periods during the night.

In September 1981 first scientific dental research results were published tracing the incidence of milk-tooth caries to children's tea products for babies and infants, who continuously sucked it: the so-called baby-bottle-syndrome. At the time of the *"Milupa"* case, the "*Milupa* -children's herbal tea-drink" (*"Milupa-Kindertee-Kräutertee-Getränk"*) had been on the market since 1975 without any warning. On the label around the tea container it said, among other things: *"Milupa-children's tea is mild and light and provides for satisfaction and an undisturbed night's rest"*. After November 1981 though, the *Milupa AG* added to the label within the preparation instructions among other things the following text: *"Hold on to bottle and do not leave with the child as sucking bottle; frequent or continuous washing around the teeth, e.g., before going to sleep, can cause caries"*. After December 1982 this text was removed from the preparation instructions and placed under the heading *"Important Notice"* (*"Wichtiger Hinweis"*). It was also

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[218] *E.g., Alete* or *Nestlé*, see Graf von Westphalen, [1994] BB (Beilage 18) 1 at 18.

bordered in black, just like the information about the content capacity and the ingredients provided further down on the label.[219]

A published brochure addressed to mothers from November 1981 contained similar instructions, among other advice concerning the soothing of the child and its high liquid need. The instruction, mentioned above, was printed within a graphically ill-conceived text flow. Correspondingly, this was also true of leaflets or pamphlets (*Merkblättter*) circulated from 17 December 1981, in which the eye was first drawn to the drink's attribute as an approved thirst killer. Also shown in a framed box were the sugar contents of different drinks, such as Coke and fruit juices. According to this, only the unsweetened apple juice showed a lower concentration. Originally, different instant tea powders, after appropriate dilution, contained a sugar portion of *ca.* 9.6 %, after 1982 the "*Milupa* - children's herbal tea-drink" contained a sugar content of 3.7 %, whereas the common orange juice contained a sugar concentration of *ca.* 9.4 % and grape juice of *ca.* 16. 55 %.

The federal health office ("*Bundesgesundheitsamt*"[220]), Berlin, had ordered by a decree of 15 April 1985[221] a warning for carbohydrate-containing children's teas reading as follows: *"Notice! (Hinweis!) The prepared tea contains substances, which allow the growth of tooth decay-generating bacteria. The growth of such bacteria is especially indicated if the tea preparation will be given frequently and over long periods of time. Therefore the tea preparation should only be served on a short-term basis and only as*

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[219] Added was also the sentence: *"After the nightly dental care generally nothing sweet should be eaten or drunk"* and under the preparation instructions it was printed " *This tea is sufficiently sweetened. Additional sweetening not necessary*", *BGH* [1995] NJW 1286 at 1286 - "children's tea III".

[220] (*BAG*), now: *Bundeinstitut für Arzneimittel und Medizinprodukte* (*BfArM*).

[221] *Bundesgesetzblatt* (Federal Health Gazette) [1985] at 189: hereafter cited as *BGB*l.

directed. Its use in baby-bottles while putting children to sleep should be strictly avoided!" But this warning, giving a more detailed disclosure about the functional connection between consuming the tea out of the particular bottles and the resultant tooth damage, was never put into effect. Instead, another warning, ordered by the federal health office on 1 January 1987, was published, after the manufacturers concerned had negotiated with the federal health office. It used the following text: *"Important Notice! The tea contains carbohydrates, which after emergence of the first teeth, and especially if used frequently and over long periods, can cause caries. Therefore do not leave children with drinking bottle as a pacifier substitute, and switch over as early as possible to cups. Do not give before going to bed."*

In the third instance the Federal Supreme Court confirmed the decision of the regional appeal court awarding compensation and non-pecuniary damages for the plaintiff in the *"Milupa"* case, concerning the caries damage to a child's upper incisors. Regarding further compensation claimed, the case was dismissed.[222] Besides the Federal Supreme Court[223] a lot of lower instance courts dealt with the phenomenon of the "Baby-Bottle-Syndrome". In contrast, concerning the warning as of December 1982, the claims against the *Milupa AG* were dismissed nearly without exception.[224] In this way the courts have

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[222] 116 *BGHZ* 60 at 66 - "children's tea I".
[223] See above: "children tea" cases I, II and III.
[224] *E.g.,*: *OLG* Hamm, decision from 31 March 1993, [1993] Neue Juristische Wochenschrift - Rechtsprechungsreport 989 f.: hereafter cited as NJW-RR; *OLG* Frankfurt , decision from 19 April 1995, [1996] VersR at 861 f.; for further decisions see Graf von Westphalen, [1994] BB (Beilage 18) 1 at 2, footnote 4.

qualified the December 1982 warning as sufficient under the provision of § 823 I *BGB*.[225] The same results were found, accordingly, in two later decisions of the Federal Supreme Court.[226]

bb. The principles confirmed and specified in the decisions

The decisions basically confirm the jurisprudence shown above, but also explain several issues which were also discussed earlier. Therefore the principles found in these decisions are not necessarily new,[227] in the sense that they consider issues that would make the existing concept of liability stricter for the manufacturer's instruction duties. But they do supplement the original principles in light of marketing developments concerning product distribution in more recent years. As well, an ever-increasing consumer consciousness has been followed by an improved understanding of consumers' protection regarding mass-produced goods. Therefore these cases need to be considered, not as mere repetitions but as timely legal adjustments, *e.g.*, concerning the influence of advertisements on consumers' attitudes to product selection and use. They are also of special importance regarding the questions of causation and fault, *e.g.*, concerning the manufacturer's own responsibility (*Eigenverantwortlichkeit*) for examination and research duties before

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[225] With the exception of the decision found by the *OLG* Frankfurt from 17 December 1993 - Az.: 26 U 27/ 92 -, in which the court found for the plaintiff in his claim against the *Milupa AG*, see Graf von Westphalen, [1994] BB (Beilage 18) 1 at 2.

[226] See above: "children's tea" cases II and III.

[227] The issues are rather to be considered as extended aspects concerning the manufacturer's responsibilities. Especially important are two issues which emerged in the course of the "children's tea"*decisions*, namely, the duty to make plain to the consumer the functional connection between the danger's origin and the possibility of injury, and the manufacturer's own responsibility to take the initiative in testing their products before and after putting them on the market.

product distribution. The principles for allocation of the burden of proof, which have been more clearly specified, will be discussed in detail in the following section.

(1). Formal requirements or conditions of warnings

(a). The case-law

(aa). The Federal Supreme Court

It seems that the Federal Supreme Court continues to confine the formal conditions of a warning to the summarizing term "clear".[228] According to this case law, this requirement is not met if, for example, important warnings about a product's inherent dangers and their incidences are hidden amongst the detailed "small print" on application and dosage instructions and advertisements.[229]

Additionally the Federal Supreme Court emphasizes that the manufacturer has to make sure that warnings are attached to the product's container. Accordingly he has to make sure that necessary warnings will not be given only in loose-leaf form, and so be prone to being easily lost.[230]

In another context the Federal Supreme Court describes the requirement of a "clear" instruction or warning with the general statement that the Court's jurisprudence has demanded on different occasions that manufacturers, under the rubric of a clear indication

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[228] Graf von Westphalen, [1994] BB (Beilage 18) 1 at 3 ff.
[229] 116 *BGHZ* 60 at 68 - "children's tea I"; 99 *BGHZ* 167 at 181 = *BGH* [1987] NJW 1009 at 1012 - *"Honda"*, with reference to *BGH* [1960] VersR 842 at 843 - *"Fußboden-Klebemittel"*.
[230] *BGH* [1960] VersR 842 at 843 - *"Fußboden-Klebemittel"* ("floor covering adhesive").

of a product's specific dangers and consequences, have to provide an unambiguous, unequivocal (*eindeutig*), meaningful (*sinnvoll*) and unmistakable (*unmißverständlich*) notice of the full extent of the risks involved and the product's inherent side-effects. This must be done in the user instructions enclosed in the package provided to the ultimate consumer.[231] The appropriate standard of explicitness is expressed by the terms unequivocal and obvious (*sinnfällig*).[232]

This shows that it depends on the circumstances of each particular case, whether the formal contents or conditions of the warning are itemized sufficiently to be "clear", as described. In this way a definite, objectively provable itemization of the formal warning duties can not be definitively laid out.[233]

The *"Milupa"* decision from 12 November 1991 is on all fours with this jurisprudence. This decision also picks up the point that important instructions or warnings about product dangers and their avoidance have to be designed "clearly". Concerning the warnings given in November 1981 and December 1981, the Federal Supreme Court found them insufficiently clear and lacking prominence, because they had been given within the frame of the instructions for preparation, without especially pointing them out as warnings.[234] Also insufficient in the Court's view was the warning given in the brochures from 30 November 1981, because it was printed within a graphically ill-designed text

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[231] *BGH* [1986] NJW 1863 at 1864 - *"Überrollbügel"* ("roll barr"); observation: these findings already include substantive issues, but they sometimes overlap with formal matters, depending on the point of consideration.
[232] *BGH* [1972] NJW 2217 at 2220 f. - *"Estil"*.
[233] Graf von Westphalen, [1994] BB (Beilage 18) 1 at 4.
[234] 116 *BGHZ* 60 at 68 - "children's tea I".

flow and therefore at least the consumer familiar with the product could not be expected to realize the significance of the words or their character as a warning. The same applied, according to the Court's findings, to the notices, leaflets or pamphlets circulated from 17 December 1981, because also as a result of its inconspicuous or unobtrusive (*unauffällig*) design - both from a graphic and printing perspective - it was not well devised to come to the notice of casual consumers, familiar with the product.[235] Finally it was decided that the December 1982 warning, within the label's text flow, even though black bordered and under the heading *"Important Notice!"*, was still not good enough. The Court expressly left the point undecided, whether the warning - deemed to be short in verbal explicitness and clarity in relation to the warning demanded by the federal health office - could have been considered sufficient to satisfy the formal requirements towards new consumers.[236] But as regards consumers familiar with the product, the Court pointed out that for them in any case the warning did not signal such a significant change that the product user would have felt obligated once again to examine the entire package text closely, as the graphical design and the colour-layout had stayed the same. The less so, considering the fact, that the defendant-manufacturer also distributed the bottle, which did not provide a corresponding warning, even though it was usable for any other liquids.[237]

The Court's decision from 1994 - *"children's tea"* II - does not go any further in developing this general, formal approach, that a warning of consequences ought to be

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[235] 116 *BGHZ* 60 at 69.
[236] 116 *BGHZ* 60 at 70 - "children's tea I"; *BGH* [1995] NJW 1286 at 1287 - "children's tea III".
[237] 116 *BGHZ* 60 at 69 f.

"clear".[238] In contrast to that the Court affirms in its 1995 decision - *"children's tea"* III -, that the warning as of 12/1982 does meet the required conditions towards consumers using the product for the first time.[239]

(bb). Arguments of the Federal Constitutional Court (*Bundesverfassungsgericht*[240])

The Federal Constitutional Court, in an order denying leave for a hearing,[241] confirmed the principles found in the Federal Supreme Court's jurisprudence concerning the manufacturers' duty to warn in the "children's tea" decisions, finding the warning of 12/1982 in its contents and design quite sufficient.[242] To begin with, the Federal Constitutional Court explicitly held, as consistent with sound constitutional law, that litigation conducted at the highest court level in civil matters poses distinctly higher requirements, depending on the measure of the danger and may make higher demands regarding the design of warnings, if dangers to health and life are to be feared. The Court, addressing the warning's design, agreed with such a graduated differentiation depending upon the extent of the danger. This reflection was deduced from the assumption that the consumer would most likely not even take notice of a warning concerning especially

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[238] *BGH* [1994] VersR 439 at 440 - children's tea II".
[239] *BGH* [1995] NJW 1286 at 1287.
[240] *BVerfG*.
[241] The complainant (*Beschwerdeführer*) had objected to decisions of the *LG* and *OLG* and especially claimed that the courts had been also legally incorrect in finding the new warnings as of 12/1982 to be sufficient. In Germany the *Bundesvefassungsgericht* can be addressed if somebody finds himself treated unjustly in light of constitutional law, or violated in his constitutional rights (here: Art. 2 II S. 1 *Grundgesetz-GG*) by a Court's decision. However the complaint will not even be accepted for decision if it does not have general importance concerning constitutional law or is not found necessary for protecting somebody's constitutional right, (§§ 93 a II, 90 I *Bumdesverfassungsgerichtsgesetz-BVerfGG*).
[242] *BVerfG* [1997] NJW 249 ff. = *BVerfG* [1996] Der Betrieb 2382 ff.

severe dangers, *e.g.*, life threatening ones, if all warnings of dangers great and small were always presented in an equally striking way.[243]

(b). Scholars' opinions

At this point only those aspects will be mentioned, which have not already been subject to the courts' decisions.[244]

Focusing on the consumer's point of view, warnings must above all be easy to notice, plain and intelligible to everyone. This even requires that the manufacturer make sure that important warnings as well as, for example, any changes in package inserts, have to come to the user's notice, by use of some striking design or some arresting method of printing (such as: bold, slanted or colored), so that it will be certainly recognizable.[245] Consistent with additional suggestions, which are also on the same wave length with the requirement of a clear warning, have been a local separation of the warning, *e.g.*, by text framing or headings like "Warning", "Attention!", "Caution!" "Important Notice!". Also the prevention of overpromotion, as by watering down important warnings, by placing them in between advertising information, likely to give rise to a particular feeling of safety in using the product.[246] This happened in the *"Milupa"* case with it's recommendation of the tea as a good-night-drink or the reference made to the tea as doing good and as

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[243] *BVerfG* [1997] NJW 249 at 250.
[244] For a detailed overview on different scholarly opinions, see Graf von Westphalen, [1994] BB (Beilage 18) 1 at 4 f.
[245] Kullmann in: Kullmann/ Pfister, Kza. 1520 at 36; similar also: Schmidt-Salzer, [1972] NJW 2219 at 2219.
[246] Graf von Westphalen, [1994] BB (Beilage 18) 1 at 12, Fahrenhorst, [1994] JuS at 291 with reference to *BGH* [1972] NJW 2217 at 2220 - *"Estil"*.

providing satisfaction and an undisturbed night's rest[247]. A further aspect considered was, that the language used must be understandable for the circle of consumers addressed, without needing any further conclusion to be drawn and without use of technical terms or foreign words.[248] It was also concluded, as already mentioned in the context of the *"Estil"* decision, that a warning must be appropriately complete, explicit and detailed (*substantiiert*). In this regard the Court was suggested that it might not be enough only to point out or refer to the danger. If necessary the instructions have to inform as to how the product can be used without danger, what kind of preventive measures need to be taken, and which modes of usage have to be avoided.[249]

(c). Opportunity to take reasonable notice; obligation to take notice

As a controlling consideration in cases where a warning might, in view of the conditions set forth above, be considered as sufficient, it always has to be asked: has the manufacturer brought the contents of the warning in a reasonable manner to the attention of the product consumer? In the literature the manufacturer's duty to provide his product with a clear warning, also covering forms of product misuse, correlates to an obligation on the consumer's part to take notice of the warning, at least if he can be expected to do so on the grounds *inter alia* of its graphical, textural and color design.[250] This results from every consumer's obligation to heed his own interests. For this reason the consumer is not

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[247] 116 *BGHZ* 60 at 71 - "children's tea I".
[248] See reference made by Graf von Westphalen, [1994] BB (Beilage 18) 1 at 5.
[249] Schmidt-Salzer, [1972] NJW 2219 at 2219; observation: this again could also be considered as a materiel aspect.
[250] Graf von Westphalen, [1994] BB (Beilage 18) 1 at 11.

allowed, by renouncing any responsibility for his own safety, to put onto the manufacturer such product risks as will only arise out of misuse, contrary to the intended ordinary use. This is because the manufacturer's instruction duty is only a subsidiary one, because it is only supposed to provide for the responsible control of danger by a reasonable consumer.[251] This duty is only a fine-tuning or corollary to the manufacturer's responsibilities in producing or manufacturing. In addressing the risk of foreseeable misuse, the instruction serves the purpose of compensating for any foreseeable, predictable risks, which could not be eliminated by producing a safer product as such. *E.g.*, in the case of the "Baby-Bottle-Syndrome", the remaining risk which needs to be eliminated by warning, would only be realized if the sugar-containing tea was consumed over a long period of time, as well by day as night, and contrary to its intended use.

In conformity with this, the Federal Constitutional Court has also emphasized the consumer's own responsibility with explicit clarity. Considering the fact, that the warning from December 1982 was found to provide for the opportunity to take reasonable notice of any necessary information, the Court did not see any reason why manufacturers should be additionally burdened with increased duties due to the consequences of the baby-bottle-syndrome, which are in fact due to the negligent or careless conduct of the complainant's parents, even though they would share this negligence with a large majority of parents. The Court held that the requirements laid on the parents by way of

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[251] *BGH* [1994] VersR 439 at 440 - "children's tea II".

joint responsibility for their children's health were not such as to overstep the bounds of reason.[252]

The aspect of an obligation resting on the consumer, arising out of one's responsibility for one's self, to take notice of warnings reasonably brought to his attention, was found to be even greater in the case of long-term users. This is because the responsibility of a long-term product consumer for his consuming habits is enhanced, in comparison to the measure of self-concern which can be expected of a first-time user.[253]

A consumer continuously using the same product owes on his part a responsibility to reflect upon the consequences of the long-term use of the product and concurrently has a duty to take notice of warnings given in connection with the product's long term use.

(2). Material requirements or conditions of warnings

Besides the formal requirements, warnings also have to meet certain substantial conditions concerning contents. These will be analyzed in the following section of this thesis. So far, we have noted the substantive requirements that the manufacturer is obliged to warn about any dangers inherent in the product's ordinary use. In this connection the warning is basically determined by the average user expectation regarding the particular product, which means that a warning is not needed where the awareness of those risks is regularly part of the experience and knowledge-level of the circle of consumers in question. Under certain conditions this obligation even extends to warning

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[252] *BVerfG* [1997] NJW 249 at 250.
[253] Graf von Westphalen, [1994] BB (Beilage 18) 1 at 12.

about dangerous consequences, resulting from misguided applications not meeting the standards of intended ordinary use, if those circumstances were reasonably foreseeable by the manufacturer and the manner of use could in the broadest sense still be considered as lying within the ambit of the generally intended purpose of the product's use. A limit was imposed on situations where the product misuse was so remote that it did not have anything to do with the generally expected purpose of use. However, the border between ordinary use of a product, including reasonably foreseeable misapplication, and obviously excluded misuse is a fluid one and has to be reserved to the judge's discretion, which needs to be made after consideration of the legitimate expectations of the public.[254]

(a). The required itemization of the imminent or threatening danger: "warning of consequences" (*Folgenwarnung*)

Regarding substantive conditions, the Federal Supreme Court requires that instructions and warnings, giving clear designation of specific dangers, must unequivocally and obviously inform of the full extent of known risks involved in using the particular product, including any imminent extraordinary consequences.[255] It is not enough to give only general instructions as to how to behave. One must also inform about the damage expected if the warning be disregarded or neglected. This is sometimes expressed by the term "warning of consequences" (*"Folgenwarnung"*)[256], as distinct from the term

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[254] Fahrenhorst, [1994] JuS 288 at 290.
[255] *BGH* NJW 1972, 2217 at 2220 f. - "*Estil*".
[256] *BGH* [1994] VersR 439 at 440 - "children's tea II"; see also Graf von Westphalen, [1994] BB (Beilage 18) 1 at 14-16; observation referring to p. 15: It is not quite clear, if von Westphalen intends to express a slightly different definition by using the term "*Folgenwarnung*". It seems as if he is of the opinion that "*Folgenwarnung*" follows the "*Anwendungswarnung*" ("application warning"), *i.e.*, in the sense of a warning "following" the warning about the required application. In my opinion the Court rather wanted to

"application warning" (*"Anwendungswarnung"*)[257], which refers to instructions giving warning advice for consumers' conduct, such as *"Hold on to the bottle and do not leave with the child as a sucking bottle"*, or *"After the nightly dental care generally nothing sweet should be eaten or drunk"*. This means that instructions must be explicitly detailed and above all complete, regarding the information given about any dangers resulting from the product's application and about its consequences. Following that it might not be enough to refer only to the danger. If necessary the consumer needs to be informed about how the product can be used without danger, what kind of preventive measures need to be taken, and which modes of use have to be avoided[258].

This obligation to give consequence warnings, over and above the duty of giving warnings as to proper use, developed out of the experience that pure use warnings of the latter kind are not sufficiently taken into account, often due to ignorance or an underestimation of risks and their consequences.[259]

Accordingly, the Federal Supreme Court held that the nature of the danger has to be pointed out clearly, because the consumer must be put into a position where he is fully able to grasp it comprehensively.[260] This means warnings must be formulated in their contexts so that the dangers become plausible to the consumer's understanding, without

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use the term "*Folgenwarnung*" to define the part of the warning which informs about the threatening dangerous consequences resulting from the product's use. This means the "*Folgenwarnung*" can precede the "application warning" -additionally required in view of a sufficient warning - or can follow it, as the term used reflects the material substance of the warning's contents and by no means describe the positioning of this part in the context of a warning.

[257] *BGH* [1994] VersR 439 at 440 - "children's tea II"; see also Graf von Westphalen, [1994] BB (Beilage 18) 1 at 14-16 and my observation in the previous footnote.

[258] Schmidt-Salzer, [1972] NJW 2219 at 2219.

[259] *BGH* [1994] VersR 439 at 440.

[260] 116 *BGHZ* 60 at 68.

his necessarily having to draw his own conclusions. Here it would have been necessary to refer to the full extent of the specific risks of the "Baby-Bottle Syndrome" and warn about it, because the serious consequences of continuously washing carbohydrate liquid around the teeth were up to a certain time generally unknown to the public[261]. This applied to the bottle and mouthpiece manufacturers, because their products did direct the stream or flow of the drink directly onto the tooth parts especially at risk; and to the tea manufacturers, because their product was primarily intended to be used with these bottles.[262]

This was sufficiently achieved with the warning given by the *Milupa AG* after 12/1982, as it circumscribed the threatened danger by referring to the phenomenon of *"frequent or continuous washing around the teeth"*. Furthermore, it said that *"after the nightly dental care generally nothing sweet should be eaten or drunk"*. This was a sufficiently clear description of the problem. The warning so given as of December 1982 was adequate, because it complemented generally expectable consumer knowledge, that the consumption of sweet things is harmful to teeth.

(b). The required itemization of the functional connection and cause of the threatened danger

The duty to avert danger under the provisions of § 823 I *BGB*, in the context of false use or misapplication of a product, which results in severe body or health injury requires from the manufacturer - beyond providing the consumer with a warning as to its use and consequences of its misuse - an effort to make clear the potential causal and functional

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[261] *BGH* [1994] VersR 439 at 440 referring to 116 *BGHZ* 60 at 67.

connections between the consumer's conduct - here: leaving the child with the bottle for continuous sucking - and the danger potentially caused thereby - such as in this case: caries. The intention behind the required description of such a fuctional connection is aimed to make it possible for the consumer to realize why the product is dangerous.[263] This is of importance in the present case, for example, because the specific risk of the "Baby-Bottle-Syndrome", causing caries danger, lies in continuously washing around the inner side of the upper front teeth and the washing away of saliva protection at the same time.[264] The purpose of describing the functional connection to the consumer is to inform him about why, and in which serving mode, the product's use involves risks.[265]

In the warning from 12/1982 the causal and functional connection of the "Baby-Bottle-Syndrome" was sufficiently shown by giving an application warning in the beginning of the text saying: *"Hold on to the bottle and do not leave with the child as a suckle bottle"* and another one finishing with the words: *"After the nightly dental care generally nothing sweet should be eaten or drunk."* Thereby it was made clear that the parents of the baby were responsible to make sure that continuous sucking needed to be avoided, and especially, that drinking bottles should not be used for soothing the baby to sleep after the nightly dental care. In the framework of this application warning was placed the consequence warning presenting the functional connection, saying: *"frequent or continuous washing around the teeth, e.g., before going to sleep, can cause caries"*. This

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[262] *BGH* [1994] VersR 439 at 440 referring to 116 *BGHZ* 60 at 65.
[263] 116 *BGHZ* 60 at 68; confirmed by the Federal Supreme Court in *BGH* [1995] NJW 1286 at 1287 - "children's tea III".
[264] *BGH* [1994] VersR 439 at 440; confirmed by the Federal Supreme Court in *BGH* [1995] NJW 1286 at 1287 - "children's tea III".

made clear the potential causal and functional connections between the phenomenon of continuous sucking and the potential cause of caries.[266]

Such an illustration of the functional and causal connections was found *"especially necessary, if"* for example advertising statements that *"children like the tea as a good-night drink before they go to sleep"* and that the product also *"provides for an undisturbed night rest"* had already counteracted, in the consumer's imagination, any idea that the product could somehow be dangerous in this way.[267] This means, even though the advertisement does not itself generate liability, it may tend to intensify the duty of care already produced by the dangerousness of the product.[268] This is obviously because a consumer with a naturally existing suspiciousness towards a product, which would automatically call forth carefulness and therefore naturally protect him against dangers or risks arising from the product's use, can be lulled into a feeling of unwarranted safety by an advertisement, one that is intended to influence the consumers' attitude towards a product and impart to it an image of harmlessness[269] or possibly even play down any risks involved.

3. Causation and attribution of responsibility

To establish liability under § 823 I *BGB* in product liability cases based on the duty to warn, the injured party - as already explained above - needs to show the *haftungsbegründende Kausalität* or *Zurechnungszusammenhang* (causal connection

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[265] *BGH* [1995] NJW 1286 at 1287.
[266] *BGH* [1995] NJW 1286 at 1287; Graf von Westphalen, [1994] BB (Beilage 18) 1 at 15.
[267] 116 *BGHZ* 60 at 68.
[268] Fahrenhorst, [1994] JuS 288 at 291.

constituting actionability). This involves showing that the defendant's conduct, here the manufacturer's breach of the duty to instruct and warn the product user, caused the plaintiff's *Rechtsgutverletzung* (violation of interests or interference with the plaintiff's "absolute right" as protected by § 823 I *BGB*).

As discussed above, this is done in German liability law by the "but-for" test of the *Äquivalenztheorie*, by the theory of adequate cause (*Adäquanztheorie*) and by the "scope-of-the-rule" theory (*Lehre vom Schutzzweck der Norm*).

Under the scope-of-the-rule theory, damage cannot be recovered if the harm caused - though caused according to the *Äquivalenztheorie* and *Adäquanztheorie* - is not considered to lie within the ambit of the protection aimed at by the rule in question[270], namely, if, *e.g.*, the harm is not the mischief which the law was designed to prevent. This, however, deserves special attention in cases of violation of the duty to instruct or warn. This is because in general the harmful or damaging consequence caused by the violation of the duty to avert danger under delict law does fall within the scope of protection provided by § 823 I *BGB*, for this is fairly comprehensive. But in product liability cases exceptions do occur, especially in the context of instructional or warning duties.

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[269] Expression used by Federal Supreme Court in *BGH* [1995] NJW 1286 at 1287 - "children's tea III".
[270] *BGH* NJW 1958, 1041 at 1042; 1972, 195 at 198; *OLG* Köln NJW-RR 1994, 91 at 92 - "insect repellent spray" case; Heinrichs in: Palandt, *BGB Vorbem. v.* § 249 para 62 at 253.

a. The plaintiff's own knowledge about the product's dangers to be warned against

Because the instruction duty is supposed to enable the consumer only to assume responsibility for his or her own safety, such instructions are not required, if and insofar as the product user has the relevant safety information at his disposal and it is present to him in the concrete case. This means the question of liability towards each injured product user is always dependent upon his particular knowledge or awareness of the danger. *I.e.*, according to the Federal Supreme Court, what matters is whether the manufacturer was obligated to give warnings towards this product user.[271] This displacement of the manufacturer's obligation to warn, or in other words the Court's opinion that the manufacturer's duty to instruct or warn may be eliminated in this context, needs further explanation, as at this point the issue of causation is at question and not the manufacturer's duty to warn as his general obligation towards the product user. The reason for this is obviously that the Federal Supreme Court wanted to express that the product user, who is fully informed or aware of the product's danger, does not even fall within the scope of legal protection provided by § 823 I *BGB*, given the particular circumstances in question. This means that even though the manufacturer still has the general duty to instruct and warn vis-á-vis any other product user, nevertheless on the level of causation, such potential liability conditions are eliminated where the non instruction or warning cannot be considered as a possible cause for the user's injury, because he knew about the very dangers that were to be warned against. According to the scope-of-the-rule theory, the duty is not applicable in regard to this particular user. This

could be explained like this: under certain circumstances - such as those described - liability cannot be found, because in light of the "scope-of- the-rule" theory these particular components of causation reach back and take effect on the level of the breach of the duty of care, leading to a legal assessment that in this case such a duty did not even exist towards this particular injured person.

Therefore the Federal Supreme Court regularly determines, in cases where compensation for damage is claimed on account of the breach of the duty to instruct or warn, whether the damage precipitating product user personally knew the danger, and a warning to him was for this reason perhaps unnecessary.[272] If he did not need any further instructions the manufacturer's liability towards him will be eliminated even though he would be liable to compensate other injured persons in damages. This is because the particular injured person in this case did not lie within the protecting ambit of the instruction duty.[273]

Following these principles, the Federal Supreme Court, on the appeal of the defendant company in the "children's tea" II decision, vacated the appeal decision of the regional appeal court and remanded it back to the appeal court, holding that the appeal court had made a procedural mistake with regard to the question: whether the defendant company had breached his instruction duty towards the plaintiff's parents? The Court in particular had ignored the defendant's request to interrogate the plaintiff's parents as to whether they were in any case aware of the risk of continuously sucking sweetened tea. On the basis of the principles explained above, the parents' own knowledge of danger would

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[271] *BGH* [1994] VersR 439 at 440.
[272] *BGH* [1994] VersR 439 at 440; *BGHZ* 116, 60 at 69f. - "children's tea" I; *BGH* [1987] VersR 102 at 104 - "*Verzinkungsspray*".

have been decisive upon the question, whether the defendant company was liable, *i.e.* if it had behaved in a manner rendering liability to the plaintiff specifically.[274]

Another illustrative example is provided by the "grill-apparatus" case, submitted by way of an application for leave to appeal to the Federal Supreme Court.[275] The question was, if the grill-apparatus manufacturer had violated his *Verkehrssicherungspflicht* by providing the following "tip" in the package information: " *you bring the charcoal to glowing by pouring a cup of spirits evenly onto the charcoal*". The Court, however, found this question could be left undecided, because the plaintiff's wife had stated that the grill-apparatus user, her husband who suffered burns, had known himself that he was not allowed to put spirits into the glowing fire to set the fire ablaze again; therefore he had carefully made sure himself, before lighting, that the glowing embers were extinguished; and had only used spirits because he was of the opinion that the fuel material was not glowing any more.[276] Because the spirits would not have ignited themselves, if the charcoal had been cooled off, the Federal Supreme Court drew the conclusion in the court order of dismissal with the words: "In this way a possible violation of the defendant's *Verkehrssicherungspflicht* was not causal for the damage which occurred".

b. The injury sustained does not correspond to the dangers to be warned against

Again on the ground of the scope-of-the-rule theory, the Provincial Court of Appeal (*OLG*) Köln dismissed a claim for material and non-pecuniary damages against a

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[273] *BGH* [1994] VersR 439 at 440 - "children's tea" II.
[274] *BGH* [1994] VersR 439 at 440.

pharmaceutical company which distributed an insect repellent spray, giving consideration to § 84 *AMG* as well as § 823 I, § 847 I *BGB*.[277] At the beginning of his vacation in Kenya the plaintiff applied the insect protection medication on his skin. The plaintiff claimed that the preparation had caused skin redness, itchiness, skin blisters and pustules. The Court stated that several conditions would have to be satisfied to establish liability under §§ 823 I, and 847 I *BGB*. Not only would it be necessary to show that the product information was lacking the necessary warning about the possible harmful consequences of applying this product, but it would have to be shown too, that this absence of the warning had caused the plaintiff's harmful reactions and that such damage was embraced by the protective purpose of the required warning. The Court held: that none of these conditions were satisfied, because the defendant would have only been obligated to warn the consumer about allergenic properties of the insect repellent, since in the past only such allergic skin reactions of the product had been observed. Furthermore, the Court held that even if the defendant had breached its duty to warn about allergic reactions, it would not be liable to compensate for the damage sustained by the plaintiff, because it had not been sufficiently certain that the symptoms described by the plaintiff were indeed caused by the absence of the warning. This, because the Court had considerable doubts that a warning about possible allergic reactions would in fact have motivated the plaintiff not to apply the insect repellent, after having weighed the pros and cons of using the product in question in the plaintiff's particular position. Over and above all that, the Court stated that those symptoms which occurred in the plaintiff's case would not be

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[275] *BGH* [1981] VersR 740 ff. -"grill-apparatus" ("*Grillgeräte*").
[276] *BGH* [1981] VersR 740 at 741.

embraced in the purpose of protection of a possible duty to warn, as the warning's purpose could possibly only have been to prevent allergic reactions, because those had only occurred prior to this incident. It could not, above and beyond that, have been to give notice of the possibility of other unwanted side-effects that might occur at some point, because there was no reason at that stage to suppose that this might happen. Were it otherwise, any pharmaceutical product would need to be supplied, without any concrete reason, with a general and wholly insubstantial warning, to the effect that hitherto unknown side-effects could not be excluded. That said, an allergic reaction of the plaintiff was not established and therefore liability of the defendant company was rejected on the ground of the scope-of-the-rule theory.[278]

c. The problem of ineffective pharmaceuticals

Another part of this problem area concerning the scope-of-the-rule theory is the case of ineffective products, as in general it is not within the protective ambit of § 823 I *BGB* to guarantee the product's suitability for its intended utilization (*Gebrauchstauglichkeit*). This is meant to be reserved for the law of contract, whereas delict law first of all has the

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[277] *OLG* Köln [1994] NJW-RR at 91 ff.

[278] Observation: In my opinion it is difficult to understand the apparent distinction between the plaintiff's occurred skin reactions and an allergic one, but this assessment should be left with the medical profession. However, the case's facts give one cause to wonder whether the plaintiff would not have refrained from taking the insect protection spray, if it had been provided with a warning about possible allergic reactions, which then most likely could have prevented the adverse reaction on his skin. This was also considered by the Court when this same assertion was made by the plaintiff, but answered in the negative, after the Court had reflected upon the further circumstances of this case, namely that in any evaluation of the pros and cons of taking the product the most dominant consideration would have resulted in a decision in favour of its application in the plaintiff's case. He had already been infected with malaria and therefore had a reason to prevent re-infection, and he had never shown any allergic skin reactions in the past; *OLG* Köln [1994] NJW-RR 91 at 92.

function of protecting "integrity interests", *i.e.*, preserving consumer safety. Even though - as already explained at length above - the Federal Supreme Court has expressed the opinion that under special circumstances the manufacturer may possibly have duties under delict law also to protect the consumer against products unsuitable for use. This is especially so in the case of distribution of products, designed to protect the consumer's property or intended to protect the consumer's life and health. In view of these protective objects the manufacturer may be obligated to meet the utility and security expectations of the consumer, which he has created by distributing his product, under general delict law principles. Notably this will be so, if the consequence of not alerting the consumer to the possible inutility or ineffectiveness of the product would be to hold him back from using other and more effective products available on the market, or from taking other measures for protection of the legal object in danger. It is therefore regularly made a pre-condition for liability under § 823 I *BGB* that the party concerned could have otherwise prevented the occurrence of the damage and that this remained undone because of the manufacturer's conduct. However, in cases of a product's unsuitability for its intended use (*Gebrauchsuntauglichkeit*), one must always carefully examine whether the product's defect - here a missing or insufficient instruction or warning - has in fact led to the result, that the consumer's expected protection of his integrity or safety interests was disappointed, or whether perhaps it was only other expectations as to the product's quality which were disappointed.[279]

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[279] Kullmann in: Kullmann/ Pfister, Kza. 1525 at 7 f.

d. Interference with the sequence of causation

The scope-of-the- rule theory also comes into play in product liability cases involving interference by the person injured or by a third party in the sequence of causation. Sometimes the person sued, who has breached his duty of care, maintains that he cannot be considered the person who caused the damage, because the violation of interests was apparently caused by the circumstance created by the defendant, where either the person later injured or a third person embarked on a certain course of conduct which precipitated the damage in the final analysis. The question, if the person setting up the first cause by violating another person's interests can be held responsible for the ultimate violation according to liability law, depends on the intended protective purpose that the concrete duty of care, arising out of § 823 I *BGB* and violated by him, was supposed to serve. This means that the question of attribution of responsibility in these kinds of cases, even though causation has been established, requires careful contemplation and analysis.[280] The application of the protective purpose view-point, however, in practical situations leads to a conceptual distinction between those cases where the injured person himself has precipitated the violation of his interests and those where a third party has caused that violation.

aa. The interposition of the injured party into the sequence of causation

The attribution of any causal responsibility to another person, for a self-endangering act of the injured party which leads to a violation of his interests, is, according to the Federal

Supreme Court, conditional upon showing that this other person in a blameworthy manner has "provoked" the injured party.[281] This "provocation" has been described to the effect, that the tortfeasor at least at the outset has set up a reasonably supportable (*billigenswerte*) motivation in the injured party for his self-endangering conduct, which for instance might be based on "obligation-fulfillment", self-defense or emergency relief (*Nothilfe*).

In conformity with this, any attribution of this kind has to be regarded as excluded in all cases where product users have deliberately inflicted damage upon themselves or have consciously applied the product contrary to its intended indicated use, even though - whatever might be the state of knowledge of other users - they know exactly about the product's dangers. *E.g.*, if a chemist, knowing that a special chemical product has deadly effects, poisons himself; or if a physician knowing about special dangerous side-effects of a drug, takes it himself in knowledge of the risks involved and these materialize in his case. Under these circumstances the damaging consequences are not within the protected ambit of the violated duty of care, because the manufacturer, although in general obligated to meet his duty of care, was not required to adjust his conduct towards this particular person, in view of the specific danger which occurred in violation of this person's individual interests.[282]

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[280] Kullmann in: Kullmann/ Pfister, Kza. 1525 at 8 f. with further references.
[281] 63 *BGHZ* 189 at 191; *BGH* [1978] VersR 183 at 183 f.
[282] Kullmann in: Kullmann/ Pfister, Kza. 1525 at 9 f..

bb. The interposition of a third party into the sequence of causation

The violation of protected interests can also be caused through the interference of a third party. For example, by a farmer who, not having been instructed or warned appropriately about the dangerous consequences involved in applying a weed killer, sprays it onto his field in the vicinity of fruit plantations of a neighbor, with the result that wind-borne spray damages the fruit trees.[283] By way of distinction from those cases mentioned earlier, here it does not fall to be considered, whether the third person - here the farmer - was "challenged" or provoked into his conduct, for instance by any action of the original tortfeasor (*Erstverursacher*). The latter moreover ordinarily has to accept the action of the third person being laid to his account under liability law, if he has not prevented the third person's "tortious" action or still worse has encouraged it.[284] This is because the "*Verkehrssicherungspflicht*" often requires precisely that a person takes measures to prevent the infliction of damage caused by third persons.[285]

An attribution of responsibility for a third person's conduct, however, is not justified, if the decision made by the third person has created a new danger[286], *i.e.* the conduct of the party setting up the first cause only constituted the background or contextual risk and merely furnished the opportunity for the third person to carry out his "action" (if *e.g.*, somebody poisons somebody else with a plant preservative). In this case the original

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[283] Example given by Kullmann in: Kullmann/ Pfister, Kza. 1525 at 11.
[284] *BGH* [1978] VersR 1161 at 1162 - "*Weidezaun*" ("*meadow/ pasture fence*"); *BGH* [1980] VersR 87 at 88.
[285] In this cases though the first creator and the third person are jointly liable under the provision of § 840 *BGB*, mentioned above.
[286] *BGH* [1971] VersR 964 at 965.

tortfeasor cannot be held responsible for the resultant damage, because his conduct did not set in train this course of events.

In conformity with this the Federal Supreme Court explained on the occasion of its *"Estil"* decision, concerning the misapplication of an anesthetic, that a third person's acts may break the chain of causation in case of an intentional or conscious misapplication.[287] This, however, would be insignificant according to the Court, even if the physician had breached the duty of care on his part as well, so long as the manufacturer's failure consisted precisely in the fact that he did not counteract to such proximate and foreseeable medical blunders. Therefore, the Court in the "*Estil*" decision demanded that the manufacturer provide a clear and distinct warning about the consequence of misapplication that had already been anticipated.[288]

4. The burden of proof

In a lawsuit to enforce a duty to instruct and warn, the plaintiff and defendant are often in dispute about questions such as: whether the plaintiff's damage was caused by the particular product in question at all, whether an instruction or warning was missing which would have been necessary, whether an instruction or warning given was insufficient or even whether a sufficient instruction or warning would have avoided the damage. In this connection it is the court's obligation to decide on all the legal matters. But it is on the litigation parties to submit the factual circumstances on which the court can base its decision. As a general rule each party has to submit and prove the factual circumstances

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[287] *BGH* [1972] NJW 2217 at 2221.

favouring or supporting the claim or defence. In court proceedings therefore it is of dispositive importance to ascertain whether the party can prove factual allegations and whether certain rules governing the burden of proof come to one's aid. In this context the most important issue is: which litigation party has to carry the burden of proof (*Beweislast*) for each dispute-deciding fact to be determined. Depending on this, the party that is not able to meet the required proof of evidence, the so-called need of proof (*Beweisnot*)[289] will lose the action on the ground of unprovability, according to the concept of burden of proof apportionment (*Beweislastverteilung*). The basic principles regarding the burden of proof have been explained above, notably that each party in the legal proceedings in general has to prove the conditions constituting the claim (*anspruchsbegründenden Voraussetzungen*). The same applies to the proof of damage, the different causation levels, and so on. In this regard a general introduction to the concept has been given above[290], so that here we shall focus on the specific situation involving instruction defects and duty to warn cases concerning causation and fault.

a. Alleviating mechanism (*Beweiserleichterungen*) for the proof of causation

As a general principle in the law of product liability, it is for the injured plaintiff to prove that the violation of his interest ("absolute right") was caused by a product defect.[291] This means, alleging the insufficiency of an instruction or the absence of a necessary warning.

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[288] *BGH* [1972] NJW 2217 at 2221.
[289] Kullmann, [1981] WM 1322 at 1329.
[290] See chapter II., 4. -6., for further details, also see the comprehensive explanation from Kullmann in: Kullmann/ Pfister, Kza. 1526 at 1-13.
[291] 51 *BGHZ* 91 at 102 - "fowl pest".

The plaintiff has to prove that the damage would not have occurred but for the "defective" instruction or the omitted warning. According to case law jurisprudence, an omission is only considered to be causal for damage consequences if the damage would have been avoided with certainty had the manufacturer acted in conformity with his duty.[292] In this context proof of a mere possibility or even probability to a certain level, is not enough.[293] The Federal Supreme Court has in principle recognized alleviating mechanisms for the proof of causation in cases of product liability by calling in the help of the *prima-facie* rule (*Anscheinsbeweis*).[294] We must now look at the special principles found in duty to instruct and warn cases.

aa. *prima-facie* evidence rule (*Anscheinsbeweis*)

Even though the Federal Supreme Court on several occasions has found room for application of the *Anscheinsbeweis* (*prima-facie* evidence rule) in the ambit of the causal connection constituting actionability (*haftungsbegründenden Kausalität*), the reasoning has always made clear that there is nc general alleviating mechanism for the proof of causation. In cases where a hypothetical cause of events concerning an individual's behaviour has needed to be determined, the Court has always stressed the need for caution and discretion in applying the *prima-facie* rule.[295]

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[292] 61 *BGHZ* 118 at 120 - "self-adhesive foil" ("*Selbstklebefolie d-c-fix*").
[293] *BGH* [1975] BB 1031 at 1032 - "*Spannkupplung*".
[294] Hans Josef Kullmann, "*Die Entwicklung der höchstrichterlichen Rechtsprechung zur deliktischen Warenherstellerhaftung*" [1978] Wertpapier-Mitteilungen 210 at 212 f.
[295] Kullmann, [1981] WM 1322 at 1329 f.; *BGH* [1980] VersR 863 at 864; *BGH* [1974] VersR 782 at 783 - "*Notarhaftpflichtfall*" ("notary's liability"); *BGH* [1981] VersR 982 at 985 - "*Anwaltshaftung*" ("lawyer's liability).

When a manufacturer breaches instruction or warning duties it will depend on the circumstances of each case, if a *prima-facie* evidence can be found to establish that the damage would have been avoided by giving sufficient instruction or warning. In this connection, it must first be shown, that actual factual circumstances exist in that particular case where it can be said that the further course of events, *i.e.* the potential conduct of the product user after receiving the necessary instruction or warning, would be preordained (*vorgezeichnet*) or at least intimated (*zumindest angedeutet*) by general life experience.[296] Real facts of this kind will in practice seldom exist because a typical pattern of conduct will generally not be determinable, as far as the individual behaviour of people in certain life situations is concerned. According to the Federal Supreme Court, use of a *prima-facie* evidence rule in such cases is only possible if a typical course or pattern of events exists in the particular case, which demonstrates or illustrates a specific cause based on general life experience and can be seen as something so common and usual that the particular individual circumstances become of secondary importance.[297]

This means that generally a *prima-facie* evidence rule does not exist to assist in proving that a required warning in package inserts and advertisements would have been paid attention to. This is because there is no observation of general experience that any consumer regularly follows such warnings. On the contrary it could more plausibly be said that life experience generally shows that not even in cases of duly attached warning signs accompanying the product does the user always react in a typical manner. This applies all the more forcibly with regard to warnings in package inserts and

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[296] See *BGH* [1974] VersR 782 at 783, re: the *prima-facie* rule in the case of the violation of a notary's obligation to inform; Kullmann in: Kullmann/ Pfister, Kza. 1526 at 15.

advertisements. Thus one must proceed on the assumption that the infliction of damage will be avoided only in a few cases by a different user instruction or a more carefully formulated advertisement, because often package inserts are not even read and advertisements most likely will be forgotten by the time the product is used.[298]

In the *"Estil"* case, however, the Federal Supreme Court recognized a *prima-facie* rule of evidence for the proof of causation, arguing that the physician applying the anesthetic injection would have paid attention to an appropriate notice and would have acted accordingly; or if this was not possible, he would have declined to use the product. Such behaviour, it was found, should have been expected as the typical and considered response of any trained and conscientious physician.[299]

Later, in the "children's-tea I" case the Federal Supreme Court proceeded on the assumption that in a case of missing warnings which would have warned clearly and understandably about specified dangers, a "*tatsächliche Vermutung*" (factual presumption) might exist that such a warning would have been paid attention to.[300] At the same time the Court explained that the person obligated to warn might be able to rebut

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[297] 100 *BGHZ* 214 at 216; 104 *BGHZ* 256 at 259; Kullmann/ Pfister, Kza. 1526 at 15.
[298] Kullmann/ Pfister, Kza. 1526 at 17.
[299] *BGH* [1972] NJW 2217 at 2221; see for a further example given in this context also 17 *BGHZ* 191 at 198; Kullmann in: Kullmann/ Pfister, Kza. 1526 at 16. In this context the "*Impletol*" case, which will be discussed later, decided by the *Oberlandesgericht* (*OLG*, regional appeal court) Stuttgart is worth mentioning, because causation could not be found, as the proof was not submitted that the injection would have been proceeded differently or not at all, since the physician had admitted, that even having received a package insert with instructions, he had not paid attention to it according to his usual practice during recent years, where this familiar product was concerned, *OLG* Stuttgart [1990] VersR 631 at 633.
[300] 116 *BGHZ* 61 at 73, with reference to: *BGH* [1989] VersR 155 at 157, Kullmann, [1981] WM 1322 at 1329; Kullmann, [1997] NJW 1746 at 1753 with further reference. The term *tatsächliche Vermutung* was criticized for being vague, open and "vapid and insubstantial"(*schillernd*), and without precise contours, Prütting, [1989] Karlsruher Forum 15 at 15.

the presumption. In this way the Court arrived at a position deduced from ordinary human experience which is tantamount to a *prima-facie* evidence rule.[301]

It seems as if the Court wanted to declare that the consideration of such a factual presumption regarding causation - to the effect that the injured party would have acted in compliance with an instruction or warning given - would be most likely in cases where instructions and warnings are of such a kind that it can be said that under normal circumstances they could not have been disregarded or neglected by the user.[302] To proceed on a presumption for causation in case of delict law would be most plausible, if the duty to instruct and warn was supposed to make plain a serious risk to the injured person, a risk which generally no sensible person would take.[303]

However, before applying these principles the circumstances in the case at hand always need to be carefully examined. Even though it has to be admitted, that sufficient warnings might generally be an effective mechanism for averting damages, in exceptional cases the injured consumer's conduct in the course of events leading to the damage can still be used to refute the presumption, that a warning would have been paid attention to, thereby avoiding the damage.[304]

On these grounds the Federal Supreme Court in the "sniffing" case objected to drawing the presumed conclusion that a clear warning about the toxicity of the refrigerant would

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[301] See Kullmann/ Pfister, Kza. 1526 at 16.

[302] Rolland, para. 123 at 377, is apparently of the view that this should even lead to reverse the burden of proof in favour of the plaintiff.

[303] Kullmann, [1981] WM 1322 at 1329.

[304] *BGH* [1957] VersR 584 at 584, where *prima-facie* evidence was denied because the injured defendant had not paid attention to obvious dangers literally jumping into his open eyes. Therefore, a sentence of

have dissuaded the plaintiffs' son from using it as an intoxicant, with fatal results, because only more or less toxic substances were suitable for this purpose. The Court emphatically stressed that in cases of intentional misuse there is no room for the application of *prima-facie* evidence.[305]

In another case the physician's conduct did not allow argument to proceed on the assumption that a sufficient warning would have avoided the damage. In the "*Impletol*" case[306] the plaintiff had suffered a painful muscle injury in his shoulder after a miss-hit with his golf club into the ground. His physician injected the local anesthetic "*Impletol*", which contains the active agents "*Procain*" (a cocaine derivative) and caffeine, into the painful area. Shortly after that, the plaintiff became unconscious, after which his breathing stopped and his heart ceased to beat. After resuscitation the plaintiff claimed damages from the pharmaceutical manufacturer, as well as the treating physicians, claiming to have suffered long term brain damage because the package insert did not provide the necessary information about the product's dangers.

Following the Court's findings the plaintiff did not submit evidence that, in the case of a sufficient warning the application of "*Impletol*" would have been carried out differently or not at all, since the physician himself had admitted that even if he had received a package insert with instructions he would not have paid attention to it, according to his usual practice in recent years concerning this familiar product. Under these circumstances even an adequate warning about, increased risks for predisposed patients in the package

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human experience to the effect that he would have taken notice of a warning sign was denied, because such would not have excluded the conduct of a gross inattention to an operating fault.

[305] *BGH* [1981] NJW 2514 at 2516 - "sniffing".

insert, would not have come to the physician's notice and consequently could not have avoided the application of "*Impletol*" in the case at hand.

bb. Availability of other alleviating mechanisms for the question of causation: reversal of the burden of proof?

(1). Violation of the duty to explain in cases of contracts

In cases of contractual obligation to provide explanatory information, the case law of the Federal Supreme Court has recognized the reversal of the burden of proof in favour of the plaintiff regarding the question of causation, as to how the plaintiff would have acted if the other party had made him aware of the possible risks involved, in conformity with his duty.[307]

In one of these cases the plaintiff had used in his hairdressing salon a hair tonic manufactured by the defendant company, and this tonic had caused irreparable skin reactions on his hands. The package inserts in the wholesale packages sent to hairdressers did not warn about the risk of possible allergic reactions to the hair tonic, here irreparable polyvalent hyper-sensitivity, even though those harmful effects had been discovered during its clinical testing. Reflecting on the question of the burden of proof for the causal connection between the omitted warning and the damage caused to the plaintiff, the Court stated that the contracting party who has violated his duty to instruct or warn has to carry

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[306] *OLG* Stuttgart [1990] VersR 631 at 633.
[307] 61 *BGHZ* 118 at 120 ff. - "*Selbstklebefolie d-c-fix*" ("self-adhesive foil"); 64 *BGHZ* 46 at 51 - "*Haartonicum*" ("hair tonic") - = *BGH* [1975] NJW 824 at 825; *BGH* [1977] WM 1027 at 1028 - "*Pflanzenschutzmittel*" ("plant-protective agent").

the risk of provability of this causal connection.[308] With this case law the Federal Supreme Court has provided a solution for the difficult, perhaps insuperable, problem of proving a hypothetical cause of events, a task normally resting on the plaintiff; namely, to prove that the damage would not have occurred if the defendant had acted in conformity with his duty. According to the Court, the duty serves to prevent the unfair consequence which ensues if a contract party violates his contractual duties and escapes liability by the mere assertion that the causal sequence of events would not have been different if he had acted in conformity with his duty. The risk of such unsolvable circumstances should rest on that party who has created it by his conduct in breach of his duty.

The Court supports its reasoning primarily by focusing on the purpose of contractual duties of explanation, which is to enable the contract partner to make his own decision about steps that might involve risks of damage. It takes into account, that the supposed purpose of such contractual explanation, instruction or advice duties is, *inter alia*, to help clarify whether the contract partner, had he been made aware of the entire scope of the particular risk involved, and would have still proceeded with the intended measure, in this case using a product or not. The explanation is supposed to serve the purpose of overcoming the oft-occurring dilemma of proof, stemming from the fact that after the events it is difficult to assess, with necessary certainty, how the person concerned would have acted or decided if given timely information about possible damage-threatening dangers. One purpose of the duty to inform is to guard against this problem. Therefore the particular interests of the plaintiff involved demand that, if the question of causation can

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[308] *BGH* [1975] NJW 824 at 825 -"*Haartonicum*" ("hair tonic") -, referring to 61 *BGHZ* 118 at 122 "*Selbstklebefolie d-c-fix*" ("self-adhesive foil").

only be decided hypothetically, he is to be relieved of this onus of proof which otherwise would rest on him.[309]

Despite the newer approach in contract law the Federal Supreme Court, in the context of liability under § 823 I *BGB* in the normal breach of the duty to instruct and warn cases, still proceeds on the assumption that the onus of proof for the causal connection rests on the injured product user. The injured party has to prove that his harm would have been avoided, if he had been sufficiently warned about the risks.[310] In the area of delict law any reversal of the burden of proof was already found to be questionable, because it did not in general follow from of the specific purpose of the explanation duty which has been violated. In contrast to the contract situation, the warning and instruction duties developed from *Verkehrssicherungspflichten* are purely behaviour-oriented obligations, not result or consequence-related.[311] Therefore, it was found that, if in the case of a violation, a shifting of the burden of proof was generally accepted, it would equate with consequence-related responsibility duties arising out of contract law.[312]

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[309] *BGH* [1975] NJW 824 at 825 - "hair tonic".
[310] *BGH* [1975] BB 1031 at1032 = *BGH* [1975] NJW 1827 at 1829 - *"Spannkupplung"*; *BGH* [1987] VersR 102 at 104 - *"Verzinkungsspray"*; 99 *BGHZ* 167 at 181 - *"Honda"*; 106 *BGHZ* 273 at 284 - *"asthma spray"*; 116 *BGHZ* 60 at 73 - *"children's tea"* I.
[311] 80 *BGHZ* 199 at 204 - "apple-scab II".
[312] Kullmann in: Kullmann/ Pfister, Kza. 1526 at 19.

(2). Reversal of the burden of proof in a case of physicians' liability

(a). Physicians' duty to give full disclosure

According to the jurisprudence of the Federal Supreme Court in the area of physicians' liability, concerning their duty to give full disclosure, the injured patient does not have to prove that he would have refrained from the treatment if he had been informed.[313] Here it is enough to show that he would have been in a real decision conflict (*echten Entscheidungskonflikt*). The remaining uncertainty as to how the patient would have decided, if he had to choose between two possible treatments and whether he would have given his consent to a more dangerous action, is laid to the account of the physician who has acted without a valid consent.[314]

There has been some criticism in the literature, to the effect, that the Federal Supreme Court does not apply the same rules in pharmaceutical product liability cases.[315] The difference between an omitted warning on the part of the physician or through package inserts was found to be minor, especially if one considers the fact that a pharmaceutical product prescribed by a physician is only an extension of the physician's conduct. Further, it has been pointed out that both cases involve proof of psychological or "motivational" causation, where scientifically certain results cannot be provided.[316]

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[313] 29 *BGHZ* 46 ff.; 29 *BGHZ* 176 ff.; *BGH* [1956] NJW 1106; [1961] at 2203; [1963] at 393; [1965] at 2005; [1971] at 1887; [1972] at 335.
[314] 29 *BGHZ* 176 at 187.
[315] Deutsch, [1989] JZ 855 at 856.
[316] Deutsch, [1989] JZ 855 at 856.

Nevertheless, the Supreme Court seems to regard cases of physicians' violation of their duty to give full disclosure as being exceptional.[317]. Therefore the alleviating mechanism established in these cases concerning causation cannot that simply be extended to cases of manufacturers violating their delict law duty to instruct, inform and warn.[318] It remains for future case law to make that decision.

(b). Grossly negligent maltreatment by physicians

The same is true about the case law concerning grossly negligent malpractice on the part of physicians. Here also the Federal Supreme Court has recognized the reversal of the burden of proof regarding causation in favour of the injured patient.[319] This is based on the reflection that the investigation of the course of treatment used has in a particular way been made more difficult by the fundamental importance of such a mistreatment[320]. This is so because the spectrum of possible causes for damage to the injured party has been significantly enlarged or shifted,[321] due to the complicated and complex nature of the physician's failure.

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[317] 61 *BGHZ* 118 at 123. The Court expressly stated that the physician's duty to give full disclosure goes its own way, in so far as its violation generally occurs where the patient's consent to the physician's action is missing; which then is considered to be an unlawful bodily injury and independent of the question of how the patient would have decided if fully informed, in conformity with the physician's duty.

[318] 99 *BGHZ* 167 at 181 - "*Honda*", *BGH* [1975] BB 1031 at1032 = *BGH* [1975] NJW 1827 at 1829 - "*Spannkupplung*"; *BGH* [1977] VersR 334 at 335 - "*Auto scooter*"; *OLG* Stuttgart [1990] VersR 631 at 633 with reference to *BGH* [1980] VersR 863 at 864 "swimming pool".

[319] *BGH* [1968] NJW 2291 at 2293; Kullmann in: Kullmann/ Pfister, Kza. 1526 at 20 referring to 72 *BGHZ* 132 at 133 f.; 85 *BGHZ* 212 at 216 f.

[320] Kullmann in: Kullmann/ Pfister, Kza. 1526 at 20 referring to *BGH* [1992] VersR at 238.

[321] 116 *BGHZ* 61 at 76 - "children's tea I" - referring to 85 *BGHZ* 212 at 216; Kullmann in: Kullmann/ Pfister, Kza. 1526 at 20 referring to *BGH* [1989] VersR 80 at 81.

The Federal Supreme Court has proceeded similarly in cases of grossly negligent violations regarding other professional duties, aimed at averting dangers for bodily integrity and health.[322]

Support is to be found in the literature for application of these principles in the same way against pharmaceutical manufacturers.

The deviation from the general law, which puts the burden of proof on the plaintiff, was found to be allowable and particularly exigent in view of the special and difficult situation arising in cases where hypothetical courses of events have to be proved.[323] This has been explained with the following reasoning: if the law puts the burden of proof regarding causation on the injured party, it primarily addresses the basic case of the actual causal connection between conduct and consequence. In physician's liability cases the problem is almost always the causal sequence following from omissions in breach of the required duty, *i.e.* the hypothetical result of the required conduct. These cases were found to be related to those where the actual causal connection between the conduct, contrary to the required duty (*pflichtwidriger Handlung*), and the result (*Erfolg*) is certain; and doubt only remains as to whether the result would have been averted had the required conduct been carried out.[324]

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[322] Kullmann in: Kullmann/ Pfister Kza. 1526 at 20 referring to *BGH* [1962] VersR at 541 ff. in the case of a bath attendant; *BGH* [1971] VersR 227 at 229 in the case of hospital care givers. See also Peter Hanau, "*Anmerkung zu* (commentary on): *BGH* [1968] NJW 2291 ff." [1968] Neue Juristische Wochenschrift 2291 at 2291: hereafter cited as NJW, who wants to apply these principles unrestrictedly to the disadvantage of pharmaceutical "manufacturers" and pleads for putting them into the same category with physicians.

[323] Hanau, [1968] NJW 2291 at 2291 f.

[324] Hanau, [1968] NJW 2291 at 2292.

However, principles concerning the reversal of the burden of proof in cases of medical maltreatment cannot safely be generalized, as long as the Federal Supreme Court does not include pharmaceutical product liability cases in this body of case law.[325] According to the Federal Supreme Court, the special features which have motivated the Court to diverge from the normal burden of proof apportionment do not exist in product liability cases, as the two apparently are not comparable.[326] This is because the difficulty of analysis imported to the course of events in product liability cases, created by the non-provision of - or shortcomings in - instructions, was found not to have the same relative importance as grossly negligent maltreatment, which can only be found when a medical mistake, viewed objectively from a medical standpoint, seems to be beyond understanding or justification.[327] Another possibly important ground of difference that needs to be considered in the discussion about the respective liabilities of physicians and manufacturers of pharmaceutical products is that the former renders a service directly to his patient while the latter releases products into public circulation. The distinction between things and services is one embedded in the law, even if it might not seem perfectly justifiable in this context.

In the field of product liability supposedly no case has been decided on grounds of these principles and its undifferentiated application is also rejected by opinions in the learned literature.[328] In this way it has been conceded, that this principle in general can only be considered where protective duties have remained unfulfilled as an inherent part of an

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[325] Kullmann in: Kullmann/ Pfister, Kza. 1526 at 20 referring to *BGH* [1984] VersR 40 at 41.
[326] 116 *BGHZ* 61 at 76 - "children's tea I".
[327] 116 *BGHZ* 61 at 76 - "children's tea I" referring to *BGH* [1983] VersR 729 at 730.

imagined consequence-related performance duty (*Teilinhalt einer erfolgsbezogenen Leistungspflicht*). But again, one needs to take into account, that the delict law *Verkehrssicherungspflicht* is action-related not consequence- or result-oriented. Consequently, in case of its violation a shifting or reversal of the burden of proof concerning causation, between the breach of the duty of care and the protected interests, cannot be made without further deliberation.

Following this, the reversal of the burden of proof concerning the *haftungsbegründenden Kausalität* in the area of product liability was held to be most readily imaginable, if the product manufacturer violates duties relating to his profession, which are to serve the purpose of protection of life, bodily integrity and the health of others. For instance, if he was for the sake of those objectives obligated to guarantee his products to be 100 % free of defects, such as in the case of manufacture or development of pharmaceutical products, a reversal of the burden of proof might seem justified.[329] It has been argued that in such exeptional cases the duty of care towards the public (*Verhehrssicherungspflicht*) could come close to a guarantee duty (*Einstandspflicht*) and therefore might leave room for such an allocation of the burden of proof, reversing it to the disadvantage of the manufacturer.[330] This however has been firmly rejected regarding the burden of proof for the causal connection between the violation of interests and the conduct of the product user who received no warning from the manufacturer.[331]

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[328] Kullmann in: Kullmann/ Pfister, Kza. 1526 at 20 f. with further references.
[329] Deutsch, [1979] VersR 685 at 689 with further examples, such as the manufacture of safety parts for motor vehicles, life jackets, parachutes.
[330] Kullmann in: Kullmann/ Pfister, Kza. 1526 at 21.
[331] 116 *BGHZ* 61 at 76 "children's tea I"

Nevertheless it remains to be seen, if the Federal Supreme Court will rule in a manner consistent with these ideas at some point in the future where the pharamceutical manufacturer has breached his duty to instruct or warn. One may speculate that this may depend upon whether the Court will continue to classify pharmaceutical product cases, involving the duty to warn as belonging to the field of product liability, where it was found that a reversal of the burden of proof can in no case be considered, regarding the causal connection between the violated interest and conduct of the product user who the manufacturer did not warn;[332] or whether the Court follows the physician liability cases in deference to the view point, explained above, that a reversal of the burden of proof could be imaginable, where the manufacturer could be considered to have violated professional duties intended to protect other people's lives, bodies or health.

The analysis above leads one to the conclusion that, apart from the presumption of causation under particular circumstances, mentioned above, there is no alleviating mechanism available. Only under certain circumstances can the *prima-facie* evidence rule come to the help of the injured party.

b. Alleviating mechanism (*Beweiserleichterungen*) for proof of fault and conduct contrary to the required duty (*Pflichtwidrigkeit*)

As a further condition for basing his claim on § 823 I *BGB*, the injured party has to submit proof of the defendant's fault. In the case of assessing negligent violation of the defendant-manufacturer's duty of care owed to the public generally

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[332] 116 *BGHZ* 61 at 76 "children's tea I".

(*Verkehrssicherungspflicht*), this entails submission and proof of factual circumstances which show that he has violated his external[333] or objective duty of care (*"äußere" Sorgfalt*), as well as his internal[334] or subjective duty of care(*"innere" Sorgfalt*).

Here the Federal Supreme Court has also recognized an alleviating mechanism (*Beweiserleichterungen*) in favour of the plaintiff. Since the decision in the "fowl-pest"case the jurisprudence of the Federal Supreme Court in product liability cases reverses the burden of proof (*Beweislastumkehr*) and places it on the defendant, if a manufacturing or design defect has been established.[335] In this way, reversal of the burden of proof embraces not only the subjective "inner" duty of care, but also the objective or "outer" duty of care (*objective* or *"äußere" Sorgfaltspflicht*, which equals the *objective Pflichtwidrigkeit*).[336] Because the conduct required by the general duty of care (duty to maintain public safety or *Verkehrssicherungspflicht*) is exactly correlative to the "outer" or objective duty of care as a component of the fault concept, it follows logically that the plaintiff in these cases is relieved of the burden of proving the objective violation of the initial duty of care (*objective Pflichtverstoß* or *Pflichtwidrigkeit*). This issue is allotted rather to the manufacturer, who has to provide exonerating evidence (*Entlastungsbeweis*).

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[333] Also-called *"objektiver Pflichtversoß"* or just ***"Pflichtwidigkeit"*** (conduct objectively contrary to the required duty). This is one side - the external - of fault, if the tortfeasor's negligence stands in question. This also coincides with the violating conduct, in the case of product liability cases, the breach of the duty of care (*Verkehrssicherungspflichtverletzung*), which is generally indicated by way of the objective defectiveness of the product; Rolland, para. 120 at 375.

[334] This refers to the ability of the tortfeasor to recognize the appropriate conduct in each individual case, in view of the question: can the conduct contrary to the required duty be imputed to him? This is what actually constitutes what is called ***Verschulden*** (fault).

[335] A product defect at the time of distribution that has to be considered as proved indicates the violation of the duty of care and this allows one to conclude that this breach of the duty of care is due to the manufacturer's fault, if he does not exonerate himself. Consistent case law of the Federal Supreme Court, established in the 51 *BGHZ* 91 ff. - *"fowl pest"*, has helped to overcome the problems that could not be solved with the *prima-facie evidence* rule (*Anscheinsbeweis*).

[336] 80 *BGHZ* 186 at 197.

He has to exonerate himself, by explaining the entire objective course of events, including the often doubtful question of whether the defect was or was not, according to the knowledge available at the time of distribution, recognizable or foreseeable. This is, because the product is most likely considered to be defective by virtue of conditions lying within the manufacturer's ambit of organization and risk. Therefore, it has been considered easier for the defendant-manufacturer to prove that he was not at fault, regarding each possible cause for the defect. In the case of instruction duties or the duty to warn, the situation is different. This is because the decisive moment or time at which the manufacturer can be accused of having breached his duty to instruct and warn does not necessarily correspond with the time of distribution. It can also arise at a later time. For this reason the Federal Supreme Court has differentiated between original or initial instruction defects and those which have arisen subsequently.

aa. Original or initial instruction defects

In the case of so-called original or initial instruction defects, *i.e.*, if an instruction or warning was already insufficient or missing at the time of product distribution, the reversal of the burden of proof is applicable in the same way as decided for manufacturing and design defects. This was clearly stated by the Federal Supreme Court in the first "children's tea" case.[337] If it has been determined in a product liability suit, that the manufacturer has distributed the product with an instruction defect, one must proceed on the assumption, that such a defect is based on the manufacturer's fault, unless

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[337] 116 *BGHZ* 61 at 72 f.

he is not able to prove the opposite. Concerning instruction defects already made at the time of distribution there is no basis for applying any different rule than in cases of manufacturer or design defects. Accordingly, the injured plaintiff only has to prove that a consumer's instruction was necessary. It is then on the defendant-manufacturer to submit and prove facts tending to show that he has either not "objectively" violated or has acted in a manner contrary to the required duty of care (*objektiver Pflichtverstoß*), by omitting the required warning; or, that for him "subjectively" the dangers were not foreseeable or recognizable, *i.e.* he was not at fault.

In the "*children's tea*" decision III the Court even stated that in case the instruction defect was based on the fact that the manufacturer has not warned about the product's misapplication or misuse, it does not even matter if this kind of misuse, and peril to health resulting therefrom, was generally known in medical or in other sciences. Rather what would be decisive in these cases would be whether the defendant-manufacturer knew or should have known about such misuse of his product. In this way it is also on the defendant-manufacturer to prove that those health dangers brought about through misapplication were beyond his range of vision. (In that case, the relevant danger was that of dental caries arising from continuously sucking fruit juices out of "sucking" bottles.)[338]

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[338] *BGH* [1995] NJW 1286 at 1288.

bb. Subsequently arising - reactive - instruction and warning duties

The Federal Supreme Court bases its judgment on different grounds where it has been determined that the manufacturer cannot be charged with giving insufficient instructions at the time of product distribution, but can only be accused of an instruction defect discovered from a later perspective, according to new perceptions gained outside the course of the manufacturer's business. In such cases of so-called subsequently discovered instruction defects, the Court has not relieved the injured party from proving that the manufacturer has violated his "outer" duty of care.

Accordingly, it is for the plaintiff to submit evidence or proof tending to show that the defendant has objectively violated his duty of care. Therefore in the first instance he has to prove that the defendant at the decisive time, that is, already at the time of distribution, had the duty to warn according to the knowledge then available. The question whether such a duty existed is a legal one and will be assessed by the court. However the plaintiff has to prove the factual circumstances on which the court can base its decision. This means proving that at the decisive moment when the instruction duty was required to be met, according to the standard of science and technique at that time, the product danger, neutralization of which the instruction is supposed to achieve, was recognizable; and that a reasonable possibility to avert the danger existed.[339] This was decided by the Federal Supreme Court in the "apple-scab" case I, where it was not a contested issue that after

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[339] 80 *BGHZ* 186 at 198 f. - "apple scab I"; Kullmann, [1981] WM 1322 at 1331.

product distribution there had arisen objectively a reason to warn.[340] In this case of subsequently discovered instruction defects the Court did not see sufficient reasons on substantive grounds, generally to release the injured person from his burden of proof. The Court continued that the reason for taking the burden of proof off the injured person in case of manufacturer and design defects had essentially been based on the viewpoint that he would have to explain or cast light on events which had taken place during production in the defendant's business. Different considerations, however, suggest themselves. If the manufacturer, after product distribution, finds out, or ought to have found out by way of accessible publications and experiences reported by product users, that a reason exists to issue a warning, it cannot as a rule be said that the injured party is being required to cast light on events which have taken place in an area only accessible for the manufacturer and not for the consumer. Consequently the Court has not seen a sufficient reason to put the users of products into a better position towards their manufacturers in a manner contrary to the general principles of law regarding the burden of proof. However, once the injured party has submitted proof concerning the manufacturer's objective violation of the duty to instruct which rests on him, he can be relieved of the burden of giving further proof, according to the Court's opinion, as far as the proof of the "internal" duty of care is

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[340] 80 *BGHZ* 186 at 197 ff. At the time of the court's last hearing in this case, and taking a view point as of that time, the farmers were found to have received objectively insufficient instructions, because they had not been recommended to spray the systematic fungicides, alternately with commonly used "contact" fungicides to prevent resistance development. Controversy, however, still attended the question of from what time onwards the defendant subjectively could have recognized that there was a reason to warn (as a reactive duty). This difficulty arose since the Court had determined that at least at the time of distribution the suspicion had not become so acute, that the defendant could be found to have been obligated to warn precociously in advance. The knowledge received in the meantime only gave rise to a duty to carefully examine and observe development of the product's efficiency. That the defendant would have been obligated to anything more at that time could not been determined, 80 *BGHZ* 186 at 194 f.

concerned, *i.e.* for the question, whether the manufacturer really had the corresponding opportunities to recognize or find out about the danger.[341]

The Court confirmed these principles also in the "apple-scab" decision II[342]. During its proceedings it could not be determined if the defendant-manufacturer had breached the duty to warn. The Court stated, that this lack of proof should not lead to any procedural disadvantage to the defendant. Rather, it would be for the plaintiff to carry this disadvantage in cases where he cannot trace his damage back to any defect of the product itself, but only to an insufficient user instruction. In cases of this nature, as the Court reasoned, the plaintiff at least has to prove an objective breach of duty on the part of that person, who was under the alleged duty to warn. It is a pre-condition for the establishment of an objective violation of the duty to maintain general public safety (*Verkehrssicherungspflicht*) that the duty position as such was recognizable to the defendant. This means here, that the defendant-manufacturer has only objectively breached his duty to instruct or warn, if at a point in time, at which a warning or instruction still would have been possible, it was recognizable or foreseeable according to the state of knowledge in science and practical experience that the product carried certain dangers.

In summary, however, generally in the case of instruction defects the burden of proof regarding the "internal" duty of care is reversed. Accordingly, the manufacturer has to

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Strictly speaking, this case presents an example for a reactive duty to inform and to instruct; Hart in: Hart et al., at 152.

[341] 80 *BGHZ* 186 at 199 - " apple-scab I".

exonerate himself in any case in which it is determined that he has, by omitting due warning of product danger failed to meet the required objective duty of care

cc. Critical observation or analysis

The distinctive judgments of the Federal Supreme Court reached in the "apple-scab" case I ("*Derosal*") and the "children's tea" case I might leave room to pose the question: why did the Court not feel the need to assess the legal situation for both situations in the same way?[343] However, these decisions cannot be criticized. The distinction made by the Federal Supreme Court between these two cases is not open to objection because they are based on appropriate plausible and justifiable reasons. Both cases were decided with reference to different critical points in time. Initial instruction defects are due to the manufacturer's breach of his duty of care at the time of putting the product onto the market; therefore, the Court considered such defects, like manufacturer and design defects, to be most likely to have emerged from the manufacturer's area of responsibility and business risk. Whereas subsequently arising instruction defects were found usually to arise out of further advanced knowledge subsequently received in science, technology or practical experience. Therefore different dispositive circumstances were discernible, making it only appropriate to craft distinctions such as were made by the Federal Supreme Court, with regard to the plaintiff's procedural position. It makes reasonable sense to make a judgment depending on whether the course of events that needs to be explained is rooted in circumstances that have happened in the manufacturer's business

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[342] 80 *BGHZ* 199 at 205 - "apple-scab II".

and ambit of risks, circumstances which might not even be accessible to or discoverable by the plaintiff. After all, it is the manufacturer who has developed the product, presumably tested its safety, produced it accordingly and then obviously, for whatever reason, not supplied it with the adequate user instruction or necessary warning. This tendency to shift the burden of proof, as far as events integral to the manufacturer's business are found to be decisive, was evident in both of the Court's judgments. During its reasoning in the "apple-scab I" decision[344], while considering an instruction failure relating to a subsequently discovered danger, the Court admitted that cases might exist in which the person injured will be equally in need of proof, as in cases of damage caused by manufacturing or design defects; and that occasionally, the same reasons that induced the Court to shift the burden of proof and put it onto the defendant-manufacturer might exist, in cases of detriment caused by instruction defects. Here the Court might have been thinking and referring to special cases where the new awareness which gave rise to the instruction defects was gained subsequently in the course of the manufacturer's business.[345]

The same tendency flows out of the "children's tea" decisions[346]. There the Court stated that the defendant-manufacturer cannot exonerate himself by referring to the fact that it was only after product distribution that dental-medical publications had pointed out the dangerous consequences of the Baby-Bottle-Syndrome. The Court expressed the view that it would have been on the manufacturer to investigate for himself what dangers might

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[343] Kullmann in: Kullmann/ Pfister, Kza. 1526 at 27 with corresponding references.
[344] 80 *BGHZ* 186 at 198.
[345] Kullmann, [1981] WM 1322 at 1331.
[346] 116 *BGHZ* 61 at 71; *BGH* [1995] NJW 1286 at 1288.

arise out of his product's use. On these grounds an initial instruction defect had been determined with the result that the burden of proof was reversed in favour of the plaintiff in this exceptional case.

The findings of the Federal Supreme Court are also supported by reflecting on the following considerations:

According to the principles found in the "fowl-pest" case, in product liability claims concerning a product defect in itself, it is enough for the plaintiff to prove that the product contained a defect at the time of distribution. Thereby it is never in question that the manufacturer has the duty to produce a defect-free product. The product defect indicates the breach of the duty of care which then allows one to conclude that the manufacturer was at fault, if he does not exonerate himself. In this way the reversal of the burden of proof embraces not only the subjective "inner" duty of care, but also the objective or "outer" duty of care (*objective* or "*äußere*" *Sorgfaltspflicht*, *objective Pflichtwidrigkeit*). Consequently the plaintiff in these cases is relieved from proving the objective violation of the duty of care, because this issue is integral to the manufacturer's exonerating proof (*Entlastungsbeweis*). Thus, because in case of the breach of the duty of care the conduct required by this duty corresponds with the "outer" duty of care as part of the fault concept.

In duty to warn cases, however, the claim is based on the assertion that an instruction or warning was missing, which would have been necessary. This implies logically that in the first instance it needs to be determined: whether there was an instruction or warning duty incumbent on the manufacturer. This is because only where such a duty exists can it be

breached. The question of the existence of the duty to instruct or warn is of course a legal one and cannot be determined by proof or by evidence. This will be judged by the court. However, this judgment depends absolutely on the factual circumstances submitted by the plaintiff. This shows that the plaintiff in duty to warn cases in the first instance is obligated to do more than in cases of product defects. He has to present facts to the court from which it can conclude and judge that the manufacturer had a duty to instruct or warn at some point in time, whether initially or subsequently, and to determine if it was breached. It is then in a second instance at issue whether, or to what extent, the burden of proof rests on the plaintiff regarding these factual circumstances relating to the existence of the manufacturer's duty or its objective breach. This, however, is directly related to the question whether he has to carry the burden of proof concerning the manufacturer's fault (which is dependent on whether an initial or only a subsequent duty to warn can be determined), which includes the objective violation of the duty of care, for the reasons given above.

In contrast to the cases where the product itself is defective, in a case of instruction defects the existence of such a defect can only be established if the manufacturer did not give instructions or warnings, even though from an objective point of view he had a reason to do so. This, however, can be dependent on different time periods. Depending on the factual circumstances of each case, an obligation to warn and instruct might exist initially at the time of product distribution; or, it might arise at a later time, after the product has already been put on the market. In cases of defective products it is never in question that the manufacturer has the duty to produce a non-defective product or has an

obligation to distribute only products which are not defective. Therefore the product defect already indicates that the manufacturer has objectively breached his duty of care. An instruction defect on the other hand can only arise where an instruction or warning is missing at a certain point in time, when a duty to instruct and warn exists. Therefore it is on the plaintiff to submit and if necessary to prove factual circumstances on which the Court can base its legal assessment.

Based on the factual circumstances in the "children's tea" case, the Court came to the conclusion that the defendant as a manufacturer of sugar-containing tea products for children had a duty to investigate for himself which kinds of danger to children's teeth arose out of the consumption of tea. The manufacturer was already under this duty, because he had recommended that the tea be consumed out of sucking bottles and also because he could not plausibly have remained unaware that the modern mouth pieces directed the flow of the drink onto the inner side of the upper front teeth. Furthermore the manufacturer had recommended the tea as a "good-night-drink before going to sleep" and had referred to the tea as pleasant and providing for satisfaction and an undisturbed night's rest. So the idea must have suggested itself to him that the tea would be given to children at night after dental care and also given for continuous sucking during the evening and night time. Hence, the Court found that if the defendant-manufacturer had given due consideration during product testing to the recommended use of the tea he should, as a specialist in baby nutrition, have recognized the dangers arising out of continuous sucking or tea consumption after the nightly dental care regime, even before dental science became aware of the Baby-Bottle-Syndrome through reported cases. In this

way the Court determined that the manufacturer, judged according to the standard of awareness, actual or constructive, already existing at the time of distribution, had a reason to give corresponding user instructions or warnings. At the same time this means that the defendant-manufacturer has objectively violated his duty of care, if he did not instruct or warn appropriately, as in the case at hand. Consequently the plaintiff was exonerated from the further proof of the manufacturer's fault, as it was the manufacturer's task to submit and prove factual circumstances, from which it could be deduced that the danger was not one he could or ought to have recognized.

One must distinguish those cases where an instruction or warning duty arises at a time after product distribution, by reason of newer information discovered outside of the manufacturer's business. Here the plaintiff at least has to submit and prove the factual circumstances from which it can be deduced at which time exactly the defendant supposedly objectively violated his duty to instruct or warn. In the "apple-scab" cases the risks involved in the product's use, in this instance the development of a resistance to the product, were discovered at a later time after product distribution. According to the Court's findings nothing showed that the defendant-manufacturer could have found out about that in his research department.[347] Therefore the only question was: had the defendant met his duty of product monitoring after distribution? The Court, based on the factual circumstances submitted, could not determine that the defendant-manufacturer objectively had a duty to warn about the risk of a development of a resistance to his product. This was because at a time where a warning would have still been possible, that

is before the fungicides would be used to spray the trees, the suspicion had not yet become so intense, based on the knowledge available at that time, that the defendant-manufacturer should be found to have had a reason to give precautionary warnings about the product's use. As the information that revealed the resistance development of the product was discovered outside of the manufacturer's business, the Court did not relieve the plaintiff, who based his claim on a retrospective instruction defect, of the need at least to submit and prove the factual circumstances which would show that the manufacturer had objectively breached his duty to warn.

dd. Case law decided by courts of lower instance dealing with the burden of proof and evidence in duty to instruct and warn cases

The following cases are examples in the area of pharmaceutical products, where the manufacturer's duty to instruct or warn that an objective violation could not be determined based on the facts submitted by the plaintiff or substantiated on any bases established by expert witness opinions.

(1). "Zylorik 300"

An example referring to the burden of proof is provided by the "*Zylorik 300*" case, decided by the *Landgericht* (*LG*, regional court) *Hannover*[348] and on the appeal of the plaintiff confirmed by the *Oberlandesgericht* (*OLG*, regional appeal court) *Celle*[349]. In

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[347] 80 *BGHZ* 199 at 203 - "apple-scab II".
[348] Unappealable decision, in: Sander, § 84 *AMG* case Nr. 2 at 2a ff.
[349] [1985] VersR at 148 f.

this case the plaintiff, a physician, had claimed damages from the defendant pharmaceutical company because he had sustained an eruptive skin rash followed by the temporary loss of his entire body hair (alopecia) in January and February 1981. The plaintiff alleged that his loss of hair was caused by the gout remedy "Zylorik 300", manufactured and distributed by the defendant pharmaceutical company since 1974, which he had been taking since the beginning of October 1980. The plaintiff claimed that the defendant, even though he had been aware of such side-effects for a long time, had not accordingly given appropriate warnings in the package insert or other instructions for use. The defendant company disputed first that "Zylorik 300" would have such side-effects and furthermore, that he had knowledge of such, as only two cases had ever been reported in the literature, neither of which had been able to prove a causal connection.

The Court left the question of causation undecided, because it could not even determine the defendant-manufacturer's breach of the duty to warn.

Moreover the question of whether a possible initial duty to instruct could be determined by the Court, was apparently not even seriously considered, due to the plaintiff's unsubstantiated allegations of facts; nor was the Court able to establish the defendant's duty as proceeding from a supervening or subsequently required duty to instruct. The Court argued that for the existing violation of his duty to instruct in case of such conduct on the part of the defendant, the burden of providing facts and proof (*Darlegungs- und Beweislast*) rested on the plaintiff. He would have had to prove that facts existed, from which it could objectively be deduced that the defendant pharmaceutical company was

obligated to warn against possible loss of hair when taking the drug "*Zylorik 300*".[350] Furthermore the Court found that for the existence of such an obligation on the defendant the plaintiff would have needed to prove that, according to the standard of science relevant to the defendant's conduct, the danger of such a side-effect was recognizable. This proof had not been furnished by the plaintiff.

In this connection the Court stated that the plaintiff's point could not be supported by the "expert information" dated April 1982, in which the defendant company had given notice of the possible side-effect after the plaintiff's incident (but had also denied proof of a causal connection). This, the Court explained, was because this date lay over a year after the loss of hair which had occurred in the plaintiff's case. Knowledge on the defendant's part could only be relevant if shown to have existed at a time at which the avoidance of damage would still have been possible. From the "expert information" it could be concluded that the defendant already knew, during the time of the plaintiff's incident in 1981, that his product could lead to loss of hair. The defendant admitted that two tests conducted at an early stage, which concerned the use of "*Allopurinol*" - one essential ingredient of "*Zylorik 300*" - had occasionally in the time-frame of such use been followed by loss of hair and other sicknesses, but a causal connection had not been established. Therefore the Court concluded that in view of this absence of a proven causal connection and the singular and entirely different symptoms manifested during the consumption of "*Zylorik 300*" the defendant was not obligated to consider those as side-

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[350] *LG* Hannover in: Sander, § 84 *AMG* case Nr. 2 at 3 referring to *BGH* [1981] NJW 1603 at 1605 f. = 80 *BGHZ* 186 at 197 f. - "apple-scab I".

effects and to warn against them in the package insert.[351] According to the Court's opinion, no sufficiently serious grounds existed for suspecting that such dangers had reasonably to be feared, at least not until the plaintiff's incident. Referring to the remedy's proven long term effectiveness in everyday use, the Court in this case did not even acknowledge a firm basis for the existence of such harmless side-effects as would justify belief that the defendant had violated his duty of product observation or monitoring. On the factual grounds presented, the defendant had no reason to expect that the application of his product would result in loss of hair.[352]

This decision was basically confirmed by *OLG* Celle. Based on the plaintiff's allegation of facts, the Court held that in the present case they would not even have recourse to the mechanism, available to them in principle, of officially consulting a court appointed expert witness to determine whether, at the time relevant to the case at hand, further knowledge existed which could have established the serious suspicion that "*Allopurinol*" causes loss of hair. This was because the Court found that the plaintiff had not established such circumstances, even though other pharmaceutical companies had been using "*Allopurinol*" as a gout remedy; and especially, the plaintiff as a physician must have been able to seek information about possible experiences concerning the active agent as a cause for loss of hair. The Court argued that precisely because it is possible for the consumer to inform himself about such events from outside the manufacturer's business,

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[351] *LG* Hannover, in: Sander, § 84 *AMG* case Nr. 2 at 4 referring to the "*Contergan*" decision, stating that not just any possibility of danger, however remote, would create the duty to maintain safety and to warn.
[352] Observation: I think this reasoning is slightly beyond the realm of legal assessment, but admittedly confirmed by the *OLG* Celle [1985] VersR 148 at 148 f.

he has to carry the burden of providing facts and proof to this extent and in sharp contrast to cases involving violations of the manufacturer regarding design and manufacture.[353]

(2). Mumps inoculation/ vaccination *"M/M Vax"*

Another case dealing with evidence or proof was decided by the *OLG Frankfurt* concerning a damage claim based on an alleged vaccine damage.[354] On the advice of his physician - also a defendant in the litigation - the 16-year-old plaintiff had received a mumps immunization with the vaccine *"M/M Vax"*, manufactured and distributed by the defendant, for the purpose of closing a vaccine gap discovered in his immunization record. The vaccine contained living mumps viruses and had been at that time distributed and applied worldwide, a million times. Approximately two weeks after the immunization the plaintiff was diagnosed with "*diabetes mellitus*". The plaintiff and the defendant-manufacturer were *inter alia* in dispute about the question, whether the defendant had breached his duty to instruct by not warning in the package insert about the risk of falling ill with diabetes.

The Court found that in this case the defendant had not been obligated to warn about such a risk. This was because, according to the result of evidence received on discovery (*Beweisaufnahme*), and particularly according to the specially competent explanations of an expert witness, it must have proceeded from a latently existing diabetic condition of the plaintiff already present before the mumps vaccination, and therefore was not as such

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[353] *OLG* Celle [1985] VersR 148 at 149.

caused by the vaccination but at most triggered prematurely thereby. The Court continued that, while according to the results of the evidence one must proceed on the assumption that the mumps protection vaccine has to be considered as a triggering factor for a premature manifestation of an already latent existing "diabetes mellitus", no firm scientific knowledge about the possibility of such a connection existed at the time of the plaintiff's incident. Therefore, the Court concluded that it could not be presumed that there was sufficient ground for suspicion that a duty to instruct should be considered as attaching to the defendant.[355]

(3). Inoculation for tick protection *"FSME-vaccine"*.

This case, decided by the *OLG München* on the plaintiff's appeal, again deals with damages claimed against a defendant-pharmaceutical company after vaccination damage. Four days after having received an inoculation for tick protection with the defendant's "*FSME*" vaccine the plaintiff suffered from pain in the neck-head area with Meningismus and pain radiating into the shoulder area, followed by a violent Lumbago and failure of the muscles of his foot and toe. The achilles seine reflex could not be released. The plaintiff claimed damages alleging that the defendant pharmaceutical company should have known that numerous suspicious cases of unwanted side-effects with the FSME-vaccine had been discussed and therefore should have been obligated to warn in the package-insert.

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[354] *OLG* Frankfurt [1995] NJW-RR at 406 ff., unappealable decision, the Federal Supreme Court by court order did not accept the plaintiff's appeal. The first instance had been decided by the *LG* Frankfurt, in: Sander, § 84 *AMG* case Nr. 1a at. 1 ff.
[355] *OLG* Frankfurt [1995] NJW-RR 406 at 408.

The *OLG München* confirmed the decision arrived at by the Court in the first instance, stating that the plaintiff had not even submitted proof of a causal connection between the vaccination and his health injury.[356] Although a connection could not be entirely excluded, according to the expert witness's opinion, it was held not to be likely. The Court referred to the burden of proof regarding the question of causation as resting entirely on the plaintiff. In addition, and upon consideration of the appeal pleading, the Court pointed out that there were no references to the violation of the defendant's duty in product observation or monitoring. Following the opinion of the expert witness, that the sickness which had occurred in the plaintiff's case had never been reported before, the defendant was found not to have had any reason to warn about such sequelae. The decisive moment for being made aware of such symptoms, as occurred in the plaintiff's case, would obviously have been a time anterior to the vaccination, which would have still made a warning possible.

(4). "*Tbc*" -inoculation/ vaccination

In this case the plaintiff claimed damages from the defendant pharmaceutical company, again because of vaccination damage. At the age of one month he had been vaccinated against tuberculosis with living Tbc-germs, the pathogenic properties of which had been weakened. The consequence was a mild infection, limited to the vaccination spot with the further consequence of antibody development. After that the plaintiff suffered swollen lymphatic nodes in his left groin region (*Leistenbeuge*) which later herniated and

necessitated an operation. The plaintiff was diagnosed with "lymphatic node after BCG-vaccination". In the package insert the defendant had informed that up to a 1% risk of an abscessed lymphadenitis might occur, because of which the indication for newborns and babies was supposed " to be set with particular precision and defined narrowly". The supplying office recognized the plaintiff's discomfort as a vaccination damage, giving grounds for obligatory indemnity under the provision of the *Bundesseuchengesetz - BSeuchG* (Federal Epidemic Code).

The *OLG* Celle dismissed the plaintiff's appeal and confirmed the decision of the court of the first instance. The Court neither determined an instruction defect, nor that such was the cause for the complications which had appeared in the plaintiff's case.[357] The Court argued that the plaintiff had not successfully shown that the information given in the package insert did not reflect the knowledge available to medical science. No such recognition existed at the time of the Court' decision, other than the plaintiff's incident, which could have given reason to change the instructions. Neither the governing institution nor anything in the literature had noted or observed a case similar to this one. Therefore, the Court proceeded on the assumption that the side-effects and risks of the BCG-vaccine had been described sufficiently and clearly in the package insert. But even if the information in the package insert had not reflected the existing knowledge of medical science at that time, the defendant would not have been *ipso facto* liable to compensation, because one condition for a damage claim is that the damage must result

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[356] *OLG* München [1997] VersR 314 at 315, unappealable decision.
[357] *OLG* Celle [1983] VersR 143 at 144, unappealable decision, Sander, § 84 *AMG* case Nr. 1 at 1.

from an instruction defect. This, however was doubtful because an immune defect of the plaintiff was also considered a possible cause for the severe complications in this case.

ee. Restriction of the scope of the reversal of the burden of proof in cases, where the injured party also has some other basis of claim

Legal provisions which provide for more extensive liability than is furnished by §§ 84 ff. *AMG* are not displaced, excluded or diminished in effect thereby. This is explicitly provided by § 91 *AMG*, which also declares provisions whereby another person is responsible for the damage.

Nevertheless, some opinions in the literature pose the question: whether concurring claims based on § 823 I *BGB* can still be supported by the alleviating mechanism for proof of fault found by the Federal Supreme Court jurisprudence in product liability cases as shown above? The original idea for shifting the burden of proof onto the defendant was to address the imbalance in different interests in need of protection: health interests of the injured party *versus* the "interests of the manufacturer" allow demanding from him proof of his non-culpability (*Schuldlosigkeit*).[358]

Therefore, some opinions in the literature have taken the view that, if the injured party receives compensation for one part of his damage through the established claim based on risk liability under § 84 *AMG*, for which coverage the pharmaceutical entrepreneur has to pay a heavy liability premium, the material reason (*Sachgrund*) for reversing the burden

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[358] 51 *BGHZ* 91 at 105 - "fowl-pest".

of proof regarding his fault could have lose cogency.[359] Therefore it was held, that, if the injured party can also base his claim on § 84 *AMG*, the plaintiff's interests in need of protection do not necessarily require reversal of the burden of proof concerning fault for the immaterial (or non-pecuniary) damage claim under delict law and also not regarding any damage claimed under § 823 *BGB* which exceeds the highest liability limits of the *AMG*.[360] As a further reason, it was obviously focused on the fact, that under *AMG* liability is imposed also for development defects.[361]

In my opinion, there should not be the slightest problem with the jurisprudence favouring the plaintiff because, even though the provisions of the *AMG* do not require fault, fault is required concerning all damages claimed that exceed the *AMG*'s highest limits under the provisions of § 823 *BGB*. Therefore, the alleviating mechanism should be applicable where possible according to the principles discussed above. Why should the injured party not be able to claim non-pecuniary damages[362] with the help of the reversal of the burden of proof or a claim for wider compensation than provided under AMG? This needs to be left to be decided by the courts.

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[359] Hans Josef Kullmann, "*Haftung der pharmazeutischen Unternehmer nach dem Gesetz zur Neuordnung des Arzneimittelrechts*" [1978] Betriebs-Berater 175 at 178; Kullmann in Kullmann/Pfister, Kza. 3612 at 6, Kza. 3805 at 14; Axel Sander, *Arzneimittelrecht, Kommentar* (Köln: Verlag W. Kohlhammer, 31. Lieferung January/1997) § 84 *AMG* para. 3. at 6: herafter cited as Sander, *AMG*; different Dieter Grell, "contribution to speech from Erwin Deutsch "*Die klinische Forschung am Menschen im amerikanischen und internationalen Recht*" [1987] Karlsruher Forum 11 ff." [1987] Karlsruher Forum 21 at 22.

[360] Kullmann in: Kullmann/ Pfister, Kza. 1526 at 33 f.

[361] Kullmann in: Kullmann/ Pfister, Kza. 3612 at 6.

[362] This is different in the case of working accidents according to §§ 636 I S. 1, 637 I *RVO* (*Reichsversicherungsordnung*), where the employee is generally limited to damages compensated under *RVO* and has no right to claim damages against the employer or colleagues. He has to disclaim the advantages of the delict law, including immaterial damages, because he would also receive damages if he cannot prove fault in the tortfeasor. In my opinion this is still different from the *AMG* regulations, because the *AMG* does not exclude a further basis for damage claims under delict law, which provides wider pecuniary compensation or for immaterial damages, and explicitly approves their application in § 91 *AMG*.

5. Limitation of actions

The claim for compensation for any damage arising from a delict is under § 852 I *BGB* barred by prescription after three years from the date on which the party entitled to damages actually becomes aware of the injury and of the identity of the party liable for damages; and in any case, the claim ceases to be valid after a period of thirty years following the incurring of the damages.

B. Germany's Pharmaceutical Products Act (*Arzneimittelgesetz*; *AMG*)

I. Introduction to the Pharmaceutical Products Act

1. Introductory survey of § 84 *AMG* and § 823 *BGB*

The coexistence of § 84 *AMG* and § 823 *BGB* for possible damage claims involving pharmaceutical products poses the question of their ambit of application. Both provisions are predicated upon incongruent conditions for claims (*Anspruchsvoraussetzungen*) and have different legal consequences (*Rechtsfolgen*). Some essential distinctions are:

- Liability under § 84 *AMG* concerns only certain groups of pharmaceutical products, namely drugs intended for human use which are subject to obligatory marketing authorisation, such as "finished drugs", whereas § 823 *BGB* does not know any such restriction and therefore applies to liability situations that might not be covered by § 84 *AMG*, *e.g.*, homeopathic drugs[363].
- The claim's opponent under § 84 *AMG* is the pharmaceutical entrepreneur, which is any person first placing drugs under his or its own name on the market.[364] The claim based on § 823 *BGB* is directed at the product manufacturer.

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[363] Homeopathic drugs only have to be registered as such (§ 38 *AMG*). They are not subject to compulsory marketing authorisation and therefore do not fall within the ambit of risk liability provided by § 84 *AMG*, Arno Kloesel & Walter Cyran, *Arzneimittelrecht, Kommentar*, 3rd ed. (Stuttgart: Deutscher Apotheker Verlag Stuttgart, 61. Lieferung March 1997) *AMG* § 84, para. 5 at 104 f.: hereafter cited as Kloesel/ Cyran.
[364] Rolland, in: *Festschrift für Werner Lorenz* 193 at 199.

- In contrast to § 84 *AMG*, liability under § 823 *BGB* is conditional upon fault. Whereas under § 84 *AMG*, liability is also imposed for so called "*Ausreißer*", which are by definition defective products not due to somebody's fault.
- In contrast to the liability regulations provided by delict law, § 84 *AMG* has included development risks[365] as liability responsibilities.
- A limited liability amount payable in compensation for indemnification (*summenmäßige Haftungsbegrenzung*) as assigned, intended and provided in § 88 *AMG*[366] is unknown in delict liability law. The same is true about the exclusion of liability for petty damages; § 84 *AMG* states: "...considerably injured...". Again in contrast to delict law, the *AMG* does not cover damages done to things.
- The *AMG* does not allow for immaterial (or as the common law terms them, non-pecuniary) damages (*Schmerzensgeld*), such as § 847 *BGB*.
- Under the Pharmaceutical Products Act, insurance for damage compensation is compulsory for the pharmaceutical entrepreneur (§ 94 *AMG*).

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[365] Rolland, in: *Festschrift für Werner Lorenz* 193 at 207.

[366] § 88 *AMG* provides: "Maximum amounts"
"The party liable for damages shall respond
1. in the case of death or injury of a person, only up to a capital amount of one million Deutschmarks or up to an annuity of sixty thousand Deutschmarks,
2. in the case of death or injury of several persons by the same drug, notwithstanding conditions determined in number 1, up to a capital amount of two hundred million Deutschmarks or up to an annuity of twelve million Deutschmarks.

Should, in the case of sentence 1, Nr. 2, the indemnification paid to the several injured parties exceed the maximum amounts specified therein, then the individual compensation shall be decreased to the same extent the total amount relates to the maximum amount."; translation of the Pharmaceutical Products Act throughout the paper partially based on a translation circulated by the Federal Association of the Pharmaceutical Industries' legal department, *Drug Law (Arzneimittelgesetz - AMG)*, (Aulendorf: Editio Cantor Verlag, 1992).

2. Historical background

Until 1961 comprehensive statutory regulation of transactions with pharmaceuticals did not exist in German legislation.[367] The written law was scattered in different rules of separate codes which did not meet the actual circumstances of the modern world, because the medication industry had developed from individual preparation of drugs in pharmacies into mass production. In view of this unsatisfactory legal situation the legislature aimed for legal standardisation with enactment of the Pharmaceutical Products Act[368] (*Arzneimittelgesetz*) in 1961[369]. Since then production of pharmaceuticals had been subject to personal and operational conditions; *i.e.*, manufacturing[370] of drugs was only allowed with an official license. For public control purposes, manufactured[371] drugs needed to be officially registered. Interestingly the Pharmaceutical Products Act of 1961 did not provide directions for manufacturers to test or prove the therapeutic effects and inherent hazards of products, nor did it contain examination rules or liability regulations. Therefore it was not surprising that this act was overtaken soon after its enactment by the tragic events of the "*Contergan*"-Thalidomide-case, which set the character for pharmaceutical law until the present time.[372] These experiences showed that it is not enough to bring only the security of pharmaceuticals to an optimal standard, but that it is essential to provide sufficient economical or financial protection for human beings who

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[367] Deutsch, at 450 para. 679.
[368] Term used by Markesinis, at p.81; Vieweg in: Ebke/ Finkin, at 216; another possible term used in literature is "Drug Law".
[369] *Gesetz über den Verkehr mit Arzneimitteln "Arzneimittelgesetz - AMG"* of 16 May 1961, [1961] *BGBl.* I at 533.
[370] The procedure of producing pharmaceutical products.
[371] The produced pharmaceutical product itself.
[372] Deutsch, at 451 para. 680.

suffer from drug damages despite all precautions.[373] Further drug catastrophes, caused by the appetite-restrainer *Menocil*[374], the drug *Mexaform*[375] and the short narcosis anesthetic "*Estil*", demanded a complete alteration of pharmaceutical product law in Germany.[376]

3. Legal background

In the absence of special liability regulations for pharmaceutical products legality was determined by provisions of German contract and delict law. If damages occurred through use or application of pharmaceutical products, damage claims for compensation were in general dependent on the claim opponent's fault, *i.e.*, at least his negligence. An exception to this rule, meaning liability which did not require fault, existed only in cases where a specific quality warranted [377] by the seller was missing in the drug. However, in such a case only the seller owed damages to an injured purchaser; and the seller was generally a pharmacist or a hospital, not the pharmaceutical manufacturer.

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[373] Official substantiation of the law (*amtliche Gesetzesbegründung*), Kloesel/ Cyran, *AMG* § 84 *Amtliche Begründung* (official legislature's reasoning) at 103; Sander, *AMG* § 84 *Amtliche Begründung* at 1.

[374] Mentioned by Dorothea Prütting & Hanns Prütting, "*Zivilrechtliche Haftungsprobleme im neuen Arzneimittelrecht*" [1978] Deutsche Apotheker Zeitung 256 at 256: hereafter cited as DAZ.

[375] Nervous disorders (*Nervenerkrankung*), Frankfurter Allgemeine Zeitung from 4 August 1978, "*Hoher Schadensersatz für Erkrankung durch Medikament*" (Mexaform), mentioned by Deutsch, [1979] VersR 685 at 687.

[376] Prütting & Prütting, [1978] DAZ 256 at 256.

[377] § 459 II in connection with § 463 S. 1 *BGB*. § 459 II provides:
"The seller also warrants that, at time the risk passes, the "product" has the promised qualities."
§ 463 S. 1 *BGB* provides:
"If a promised quality in the product sold was absent at the time of the purchase, the purchaser may demand compensation for non-performance instead of cancellation or reduction."

However, in the meantime the numerous damages caused by "*Contergan*"[378], for example, had shown that consumer protection could not be provided by the existing liability regulations based on fault. Manufacturers' liability could not be imposed in the event of dangerous side-effects of pharmaceutical products, which might be unavoidable according to standards of science and technology at the time of production, or simply might not be recognisable, as so called development defects. But such unrecognised or unrecognisable side-effects have to be expected from pharmaceutical products, commonly identified as "unavoidably unsafe products"[379] at any time.

These conditions created a need for liability law improvement that was more protective of injured parties, a development which would impose liability on the manufacturer independently of fault. Such regulations existed under special delict law provisions, by way of imposing risk liability for example on animal keepers[380] and car holders[381]. Such risk liability means that a person has a specific damage risk imputed on him: because he is beneficiary of this risk, he must carry the damage caused through it.[382] However, the establishment of risk liability for manufacturers was impossible by way of updating the law through the courts. Because judges were and are barred from extending risk liability outside of specially admitted codified provisions, it was for the legislative power to

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[378] The events of the "*Contergan*"-Thalidomide-case decided by the *Landgericht Aachen* (Provincial Court of Aachen), similar to those of the "*Estil*" case decided by the *Bundesgerichtshof - BGH* (Federal Supreme Court) reach back to a time before the first Pharmaceutical Products Act of 1961 came in force; Franz [1972] NJW 2217 at 2218.

[379] Kullmann in: Kullmann/ Pfister, Kza. 3800 at 5.

[380] § 833 *BGB* imposes risk liability on keepers of pet animals (*Tierhalter-Haftung*).

[381] § 7 *Strassenverkehrsgesetz*-StVG (Road Traffic Act) imposes risk liability on the car holder (*Kraftfahrzeughalter-Haftung*), which is the person who uses the car at his own expense, and not necessarily the owner.

[382] Kullmann in: Kullmann/ Pfister, Kza. 3800 at 4.

decide if and how far a stricter objectified liability could be imposed on the product manufacturer.[383]

The federal government and the federal parliament agreed that victims of pharmaceutical injuries should receive a new legal claim for compensation, one that would also yield damages, even if no culpable conduct or fault could be determined in the ambit of the manufacturer's responsibility. The question was only: how to achieve that goal?[384]

Three different models were discussed: (1) introduction of risk liability regulations in the Pharmaceutical Products Act; (2) establishment of a corporation under public law under the name "Pharmaceutical Products Compensation Fund" (*"Arzneimittel-Entschädigungsfonds"*), which was supposed to be financed by all pharmaceutical entrepreneurs through an allocation procedure; and, (3) development of a private law fund organised in the legal form of an insurance company, with reciprocity (*Versicherungsverein auf Gegenseitigkeit*).[385] None of these models have become law. Rather, an alternate suggestion has established fault-independent liability regulation[386] combined with a security provision (*Deckungsvorsorge*) at the same time by way of compulsory liability insurance in the amount of maximum liability for the pharmaceutical entrepreneur.[387]

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[383] 51 *BGHZ* 91 at 98 -"fowl-pest".
[384] Kullmann in: Kullmann/ Pfister, Kza. 3800 at 5.
[385] Kullmann, [1978]BB 175 at 175 f.
[386] Different from other cases, risk liability for pharmaceutical products was not established on the ground that a particular thing (such as animals, motor vehicles) typically produces specific dangers. Here, liability is only imposed for harmful pharmaceuticals or insufficient user information; Kullmann in: Kullmann/ Pfister, Kza. 3800 at 15.
[387] Kullmann, [1978] BB 175 at178; Kullmann in: Kullmann/ Pfister, Kza. 3800 at 6.

This fundamental reformulation was achieved by the Pharmaceutical Products Act of 1976, which went into force on 1 January 1978[388]. It reorganised the old Act of 1961, with the intent of realising an optimal provision for pharmaceutical products and of guaranteeing better security in respect of the commercial trade in drugs.[389] For this purpose all pharmaceutical products have to ensure their necessary quality, efficacy and safety.[390] Therefore, this new Pharmaceutical Products Act insists, in contrast to its predecessor, upon examination of new pharmaceutical products by an official procedure of admission. It also provides new (absolute) "risk liability"[391] regulations in favour of those injured by pharmaceutical products.

However, the legislator's expectations of the Pharmaceutical Products Act of 1976, to cover any occurring major case of damage caused by a pharmaceutical product with the new risk liability regulations, were only partially met. This was because the next big scandal was not caused by side effects of a chemical drug but occurred through contamination of blood products, with the HIV-virus and a new Hepatitis-virus, both of which were unknown until the first incidents happened.

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[388] (*Gesetz zur Neuregelung des Arzneimittelrechts*) In the Version of the Law on the Reform of the Pharmaceutical Act of 24 August 1976 [1976] *BGBl.* I at 2445, presently valid in the revised form of 19 Oktober 1994 [1994] *BGBl.* I at 3081.

[389] Deutsch, at 458 para. 694, at 476 para. 722.

[390] See reasoning to the draft for a Pharmaceutical Product Act, Bundestags-Drucksache 7/3060 at 43: hereafter cited as BT-Drucksache.

[391] For a definition see part 1, A footnote 2.

In the meantime the Act of 1976 has been amended no less than eight times[392], *inter alia* to accommodate directives from the European legislature for appropriate adjustments to the national law[393].

II. New Regulations in the Pharmaceutical Products Act of 1976

1. Principal goals

§ 1 describes the purpose as follows:

> It is the purpose of this law to guarantee, in the interest of a proper supply of drugs to humans and animals, security in respect of the trade in drugs, ensuring in particular the quality, efficacy and safety of drugs in accordance with the following provisions [to be examined below].

One major goal for the law was to achieve a maximal adjustment to international standards prevailing in other western countries.[394]

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[392] First law amending the Pharmaceutical Products Act of 24 February 1983, second law amending the Pharmaceutical Products Act of 26 August 1986, third law amending the Pharmaceutical Products Act of 20 July 1988, fourth law amending the Pharmaceutical Products Act of 11 April 1990, fifth law amending the Pharmaceutical Products Act of 9 August 1994, sixth law amending the Pharmaceutical Products Act of 20 December 1996, seventh law amending the Pharmaceutical Products Act of 25 February 1998, eighth law amending the Pharmaceutical Product Act of 7 September 1998.

[393] Fifth law amending the Pharmaceutical Product Act, Bundesrats-Drucksache 565/93 of 13 August 93 at 44: hereafter cited as BR-Drucksache.

[394] BT-Drucksache 7/5091 at 2 f.

2. Purview and scope of the Pharmaceutical Products Act

a. The definition of pharmaceutical products: drugs (*Arzneimittel-Begriff*)

The core of the Pharmaceutical Products Act is founded upon the definition of the term "pharmaceutical product" (*Arzneimittel*), also translated with the term "drug"[395], which at the same time determines the purview and scope of the Pharmaceutical Products Act.[396]

The Act sets up regulations for pharmaceutical substances, agents and compounds (*Stoffe*). It does not focus on the drug as a pharmaceutical end-product. § 2 I Nr. 1 *AMG* defines drugs as substances and preparations made from substances which, by application on or in a human or animal body, are intended to cure, alleviate, prevent or diagnose symptoms of disease, suffering, bodily injury or sickness.

According to this definition it does not matter whether the person who brought the product into public circulation designated it as a pharmaceutical product or if it in fact produces the effects attributed to it and thus is objectively identifiable as a drug.[397] What is alone decisive is whether the drug is intended to produce one of the effects designated in § 2 I *AMG*. If this is the case, then consequentially the corresponding substance or the substance preparation is a pharmaceutical product in the sense of the *AMG*. However, substances for the purpose of this law comprise, according to § 3 *AMG*, chemical elements and chemical components, as well as their naturally occurring mixtures and

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[395] For the purpose of law considered in this thesis, the two are to be used synonymously.
[396] Deutsch, at 461 para. 700.
[397] Kullmann in: Kullmann/ Pfister, Kza. 3800 at 7 with reference to Bayerischer VGH [1987] PharmaRecht 69 at 73.

solutions. Included are also plants, animal bodies (as well as human and animal body parts), micro-organisms, both viruses and their constituents or metabolic products.[398]

Conversely, and by way of anti-definition in § 2 III *AMG*, certain other specific substances are expressly excluded from the purview of the Pharmaceutical Products Act, *e.g.*, foodstuffs, tobacco and cosmetic products.[399]

As a way of dealing with any remaining or residual difficulties of definition or delimitation, § 2 IV *AMG* sets up a legal fiction or "deeming provision". As long as a product is authorised or registered as a pharmaceutical product pursuant to the Act, or is exempted from authorisation or registration by ordinance, it shall be considered as a drug (= positive fiction). If the competent federal higher authority has rejected its authorisation or registration on the ground that the product is not a pharmaceutical product, it shall not be considered a drug (= negative fiction).

Furthermore, in general practice, pharmaceutical products are subdivided into: bulk goods (*Bulkware*), *i.e.*, drugs in large amounts, in packaging not intended for direct distribution to the consumer, from which it then gets packaged into consumer-ready units; and finished drugs (*Fertigarzneimittel*), which are manufactured beforehand and then marketed in packages ready for distribution to the consumer, as defined in § 4 I *AMG*. Among the latter a distinction is drawn between drug specialties

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[398] § 3 *AMG* provides:
"For the purpose of this law, substances are
1. chemical elements and chemical compounds as well as their naturally occurring mixtures and solutions,
2. plants, parts of plants and plant constituents, whether in the processed or crude state,
3. the bodies of animals, including those of living animals, as well as parts of the body, body constituents and metabolic products of human beings or animals, whether in the processed or crude state,
4. micro-organism, including viruses, as well as their constituents or metabolic products."

(*Arzneimittelspezialitäten*), which are manufactured with consistent composition and are put onto the market in packages ready for distribution under a specific label (*besonderer Bezeichnung*), and generics (*Generics*), which are finished drugs that are brought onto the market only under their active agent designation (*Wirkstoffbezeichnung*), such as acetysalicylic acid - ASA (*Acetylsalicylsäure - ASS*) instead of Aspirin. The statutory drug definition is comprehensive because the definition for substances is so complete.[400]

b. Medical products (*Medizinprodukte*)

The enforcement of the Medical Product Act (*Medizinproduktegesetz - MPG -*[401]) makes it necessary to distinguish appropriately between pharmaceutical products - drugs - and medical products. § 2 III Nr. 7 *AMG* excludes all things which constitute medical products, appurtenances, accessories or attachments (*Zubehör*) for medical products, in the sense of § 3 MPG, from the purview of the Pharmaceutical Products Act. The legal situation presents itself as follows: things which count as pharmaceutical products are, roughly speaking, the true drugs and the substances or compounds which comprise them. Everything else, *e.g.*, an instrument, apparatus, device or any appurtenance thereto, is treated as a medical product.[402]

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[399] For a comprehensive overview see Kullmann in: Kullmann/ Pfister, Kza. 3800 at 8 ff.

[400] Deutsch, at 464 para. 702, at 466 para. 704, with further details and corresponding references on certain examples for drugs, at 464 ff. paras. 702 f.

[401] August 2, 1994 [1994] *BGBl.*I at 1963.

[402] Deutsch, at 466 para. 704. As such are also considered human-implants, like breast implants, since they have been eliminated from the ambit of the Pharmaceutical Products Act, Kloesel/ Cyran, *AMG* § 2 para. 55 at 6; Stephan Brandenburg & Hubert Erhard, *"Medizinprodukterecht"* (Heidelberg: v. Decker's Verlag 1997) para. 35 at 15.

3. Official procedure of admission (*Arzneimittelzulassung*)

According to § 21 of the Pharmaceutical Products Act new products[403] have to be approved by the Federal Institute for Pharmaceutical Products and Medicine Products (*Bundesinstitut für Arzneimittel und Medizinprodukte* - BfArM) before they can be placed on the market. This replaced the system of registration which is now only exceptionally used, *e.g.*, for homeopathic drugs. Following the American example, the establishment of an official procedure of approval and admission for pharmaceuticals was one of the major innovations in German drug law. [404] The obligation to obtain a marketing authorisation generally applies to the so called finished drugs (*Fertigarzneimittel*) as defined above. Conversely a marketing authorisation is not, for example, required for individually prescribed drug mixtures (*Rezepturarzneimittel*[405]), because these are not manufactured beforehand. On the other hand the Pharmaceutical Products Act expressly exempts certain pharmaceutical products from the obligation to obtain a marketing authorization, *e.g.*, the so called frequently prescribed drug mixtures (*Defekturarzneimittel*[406] or *verlängerte Rezeptur*) in § 21 II Nr. 1 *AMG*. These are drugs which are intended for administration to humans and, as a provable result of frequent medical or dental prescriptions, are essentially manufactured or produced in a pharmacy, as part of its normal operation, in batch sizes of up to one hundred packages ready for supply on one day and intended for sale in the one-site pharmacy. The same applies, according to § 38 I S. 2 *AMG*, to pharmaceutical products registered and distributed as "homeopathic" drugs.

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[403] This paper only refers to pharmaceutical products intended to be used by human beings, excluding any products intended for animal usage.
[404] Deutsch, at 477 f. para. 723, at 480 para. 726.
[405] Kullmann in: Kullmann/ Pfister, Kza. 3800 at 13.

Besides that, § 36 I *AMG* provides for the possibility of exempting certain pharmaceutical products from the obligation to obtain a marketing authorisation by statutory order (*Rechtsverordnung*) , to the extent that a direct or indirect hazard to human health is not to be feared, since it is evident that the requirements with regard to the necessary quality, efficacy and safety have been met. These are called standard marketing authorizations (*Standartzulassungen*).

Because the manufacturer generally is entitled to get his pharmaceutical products approved, § 25 II *AMG* has listed the negative conditions for refusing a marketing authorisation. This allows to conclude that a condition for the admission of pharmaceuticals is to present evidence that the drug has been sufficiently tested, pursuant to the presently prevailing level of scientific knowledge.[407] In addition the manufacturer has to prove his assertion about the therapeutic efficacy (*therapeutische Wirksamkeit*)[408] of the product, its pharmacological-toxicological harmlessness (*pharmakologisch-toxikologische Unbedenklichkeit*)[409] and its adequate pharmaceutical quality (*Qualität*)[410,411].

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[406] Kullmann in: Kullmann/ Pfister, Kza. 3800 at 14.
[407] § 25 subsection (2) No.2 of the Pharmaceutical Products Act.
[408] § 25 subsection (2) No. 4. of the Pharmaceutical Products Act.
[409] § 25 subsection (2) No. 5. of the Pharmaceutical Products Act.
[410] § 25 subsection (2) No. 3. of the Pharmaceutical Products Act.
[411] Hazel G.S. Marinero, *Arzneimittelhaftung in den USA und Deutschland* (Frankfurt am Main: Verlag Peter Lang, 1982) at 266 f.

4. Prohibition in respect of unsafe (*bedenklicher*) drugs

§ 5 I *AMG* prohibits the marketing of unsafe drugs, those which in the light of currently prevailing scientific knowledge, under correct and stipulated use, are reasonably suspected (*begründeter Verdacht*) of having harmful effects that exceed the bounds considered reasonable or justifiable, in the light of medical knowledge available, § 5 II *AMG*.

5. Obligation of disclosure (*Offenbarungspflichten*)

§§ 9 - 12 of the Pharmaceutical Products Act provide specific regulations for finished drugs, such as the labelling required to be displayed on the drug container or, where applicable, on the outer packages; and the instructions for use, information and warnings required in the package inserts and expert information. The reason for this is to ensure that adequate and comprehensive information about the product is given to both the experts and the consumers.[412] The material content of these regulations is important to the subject-matter of this thesis and will be looked at in detail later.

6. Prescription requirement (*Automatische Verschreibungs-pflicht*)

§ 49 I *AMG* lays down an automatic requirement of a physician's prescription for a five year period for drugs containing substances or preparations whose effects are not generally known in the field of medical science. The same applies to drugs that are preparations made from substances whose effects are generally known, if the effects of

those preparations as a whole are not generally known in the field of medical science. This is so unless the effects, as determined by composition, dosage, pharmaceutical format or application field of the preparation, are determinable. The automatic prescription requirement may be cancelled earlier, after termination of a period of three years if, by virtue of the experience gleaned from use of the drug, it is established that no direct or indirect danger exists for human health.[413]

After termination of the automatic prescription requirement, there is a further necessary prescription requirement, according to § 48 I *AMG*, if a risk evaluation shows that the drug, even under circumstances of appropriate use, jeopardises human health, when it is administered without medical supervision.

7. Pharmacy reserved drug distribution (*Apothekenvorbehalt*)

In contrast to the Canadian law, which distinguishes between prescription and over-the-counter drugs, the German law differentiates between the obligation to supply drugs only in pharmacies (*apothekenpflichtige Arzneimittel*) and over-the-counter drugs (*O.T.C. or freiverkäufliche Arzneimittel*). Drugs which are not specifically exempted for trade outside of pharmacies may only be marketed in retail by pharmacies, § 43 I *AMG*. Released for trade outside of pharmacies are only those drugs solely intended by the pharmaceutical entrepreneur to serve purposes, other than the curing or alleviation of diseases, suffering, bodily injuries or the symptoms of sickness, § 44 I *AMG*. This applies furthermore to natural and synthetic mineral, curative and sea waters, as well as tablets or

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[412] BT-Drucksache 7/3060 at 46.

pastilles, therapeutic clays, mud for mud baths, *etc.*; to plants and their parts, also fragments, mixtures of whole or cut plants or their parts as finished drugs, distillates made or juices extracted from plants and their parts, plasters and bandages for burns, disinfectants intended exclusively or mainly for external use, as well as disinfectants for the mouth and throat: § 44 subsection II No. 1. - 5. *AMG*. The general obligation to supply pharmaceutical products only in pharmacies offers an essential monopoly to pharmacies, as almost all the important drugs, especially those based on modern pharmacological knowledge, are reserved for distribution through pharmacies only.[414]

8. Obligation of notification (*Anzeigepflicht*)

Besides the consumer and the physician the competent federal higher authority is another addressee of informational and disclosure obligations of the pharmaceutical entrepreneur. Submitting supporting documents, he has to notify the competent federal higher authority forthwith of any changes occurring in the particulars and documents supplied with the application for approval, § 29 I *AMG*. Furthermore he must inform the competent federal higher authority immediately, or at least within fifteen days of receiving the knowledge, of any case of suspected side-effects or interactions with other products that can be detrimental to health. This includes any frequently occurring abuse, or extreme instances of abuse, observed in an individual case, if these can directly jeopardise human health. Changes in information as to therapy-relevant facts, such as the field of application, restriction of contra-indications, side effects, and other information required according to

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[413] § 49 IV Nr. 3 *AMG*.

§§ 10, 11 and 11 a *AMG*, are only allowed to be implemented if the competent federal higher authority has given consent, § 29 II a *AMG*. This is because, any reduction or alteration in qualification of contra-indications, side effects or interaction can always mean diminished security for the patient.

The pharmaceutical entrepreneur is also obliged to supplement any application for extension of admission by a report giving details of whether, and to what extent, the criteria by which the drug is assessed have altered within the last five years: § 31 II S. 1 *AMG*. This is to inform the competent federal higher authority about the development of the pharmaceutical product, which can be best evaluated by the manufacturer and pharmaceutical entrepreneur.[415]

A similar obligation is provided by § 49 VI *AMG*. The pharmaceutical entrepreneur must present a report on the experiences gained with drugs that fall under the automatic prescription requirement, after the termination of a period of two years after approval of the drug. This report has to give details of the quantities distributed during the period under review. Furthermore, new findings on effects, their type and frequency, contra-indications, interactions with other products, addiction, dependence or a use of the drug that is not complying with the intended purpose, shall be given. It is obvious that the competent federal higher authority does not only get early information about possible new risks, but must also receive the necessary information to assess whether the drug can be

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[414] Deutsch, at 542 at para. 824.

[415] Horst Hasskarl, "*Sicherheit durch Information im Arzneimittelrecht*" [1988] Neue Juristische Wochenschrift 2265 at 2269; hereafter cited as NJW.

released from the automatic prescription requirement, or whether it has to be put under the general prescription requirement.[416]

9. Commissioner for the graduated plan (*Stufenplanbeauftragter*)

Since the pharmaceutical law amendment of 1986, anyone who, in the capacity of a pharmaceutical entrepreneur, markets finished drugs must commission a person - the so-called commissioner for the graduated plan - possessing the required expert knowledge and the reliability necessary for exercising this function, § 63a I *AMG*. The graduated plan is drawn up by the Federal Minister, according to general administrative regulations subject to the consent of the Federal Council, which specifies the cooperation expected between the authorities and the services involved, on the various danger levels as well as on the intervention of the pharmaceutical entrepreneurs. It determines the various measures that have to be taken in compliance with provisions of the Pharmaceutical Products Act, § 63 *AMG*. The commissioner for the graduated plan is personally responsible for meeting the obligation of notification, as far as it concerns drug risks. He has to collect and evaluate information on the drug risks that become known and coordinate the necessary responses. In this way, the commissioner for the graduated plan basically has to assess the pharmaceutically immanent, as distinct from the manufacture-related, risks of drugs, and then to pass the information on to the competent authority.[417]

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[416] Hasskarl, [1988] NJW 2265 at 2270.
[417] Hasskarl, [1988] NJW 2265 at 2270.

10. Risk liability regulations (*Gefährdungshaftung*)

Besides the regulations ensuring the security of pharmaceutical products by strong requirements concerning approval, examination and distribution, the current Pharmaceutical Products Act provides special liability regulations to ensure compensation for those who suffer loss and damage caused by the production of unsafe drugs. § 84 *AMG* establishes risk[418] liability for pharmaceutical products, as follows:

> If, as a result of the administration of a pharmaceutical product intended for human use which was distributed to the consumer within the purview of this law and which is subject to compulsory marketing authorization or is exempted by ordinance from compulsory marketing authorization, a person is killed or the body or the health of a person is significantly injured, the pharmaceutical entrepreneur who placed the pharmaceutical product on the market within the purview of this law shall be obliged to compensate for the harm caused to the injured party. The liability (obligation) to compensate shall only exist if
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> 1. under correct (intended) use the pharmaceutical product has harmful effects, which exceed the bounds considered justifiable in the light of knowledge available in medical science and which have their origin either in the process of development or manufacture, or
>
> 2. the harm has occurred as a result of labelling , expert information or instructions for use (package-insert) not complying with the knowledge available in medical science.

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[418] The term "risk liability" is used as the heading for the special liability provision laid down in § 84 *AMG* and means objective, fault independent liability. However, other than in the case of former laws imposing risk liability in other fields, such as in § 833 *BGB* for animal keepers (*Tierhalter-Haftung*) or in § 7 *Strassenverkehrsgesetz*-StVG (Road Traffic Act) for car holders (*Kraftfahrzeughalter-Haftung*), liability is not imposed on the ground that a particular thing, here the the pharmaceutical product, typically produces specific dangers. Here, liability is only imposed for harmful drugs and insufficient user information, Kullmann in: Kullmann/ Pfister, Kza. 3800 at 15.

The intention of the regulation is to moderate the individual's exposure to risk and also to create a preventive effect, in the sense of encouraging manufacturers of pharmaceutical products to produce products as risk-free and harmless as possible[419]

The conditions, the legal reach and consequences of the risk liability regulations will be discussed in detail below, in the context of the different regulations concerning the legal scheme of the pharmaceutical product liability law.

III. Liability under § 84 *AMG*

1. Pharmaceuticals affected by the liability provision of § 84 *AMG*

§ 84 *AMG* does not affect all pharmaceutical products. The focus of liability - according to § 84 S. 1 *AMG* - is only considered a pharmaceutical product if, first, it is intended for human use, secondly, it was distributed to the consumer within the purview of the Pharmaceutical Products Act, and thirdly, if it is subject to compulsory marketing authorisation or is exempted by ordinance from it. Only if these three conditions are met can damage resulting from such a pharmaceutical product form the base for an obligation of compensation.

Intended for human use:

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[419] Hart in: Hart et al., *"Das Recht des Arzneimittelmarktes"*, (Baden-Baden: Nomos Verlagsgesellschaft 1988) at 158.

Pharmaceutical products "intended for human use" are those designated by the pharmaceutical entrepreneur to be administered to the human body.[420] Therefore, pharmaceutical products exclusively intended to be used in animal medicine do not fall under the liability regulation of § 84 *AMG*, even though such a product, made for animals, may be applied to a human body, for example, because of equal or similar quality to products used in human medicine.[421]

Distributed to the consumer within the purview of the Pharmaceutical Products Act:

Further, the pharmaceutical product has to be distributed to the consumer within the purview of the Pharmaceutical Products Act. The term "distribution" is used in the definition for "putting into public circulation" (*Inverkehrbringen*), as specified in § 4 XVII *AMG*. This is the keeping in stock for sale or for other forms of distribution, the keeping and offering for sale and the distribution to others. Therefore "distribution" obviously means, above all, sale in pharmacies. It also includes handing over pharmaceutical products through wholesalers to hospitals for the purpose of application to the patient[422] and distribution of samples not for sale through pharmaceutical consultants to physicians, dentists, etc.[423].[424]

"Consumer" means anyone who acquires pharmaceutical products to apply to himself or to others. Consumers also include health and sickness care institutions, where

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[420] Sander, *AMG* § 84 para. 9a at 10.
[421] Kullmann in: Kullmann/ Pfister, Kza. 3800 at 11.
[422] § 47 I Nr. 2 and Nr. 3 *AMG*.
[423] § 47 III *AMG*.

pharmaceutical products are applied.[425] The term "consumer" may be given a broad interpretation, roughly speaking, as intended to embrace all those cases where the pharmaceutical product was brought into public circulation by generally expected means of distribution for application by a consumer, regardless of whether he himself or a third person applied the product.[426] Therefore cases are also included where the first purchaser originally acquires the non-prescription pharmaceutical product to apply to himself, or receives it for the purpose of application to himself, but subsequently gives it to other family members who are to apply it to themselves personally. Once a pharmaceutical product has been distributed to a consumer, the applicability of the liability regulation will not be invalidated simply because the pharmaceutical product was subsequently given to a third person by the first acquirer, *e.g.*, because he himself did not use it up entirely.[427]

The requirement, that the pharmaceutical product has to be distributed to the consumer "within the purview of the Pharmaceutical Products Act", excludes any acquisition outside of Germany. If for example, a German tourist buys a pharmaceutical product in a foreign pharmacy which then leads to injury, he is not entitled to compensation under the Pharmaceutical Products Act, not even if: the damage only occurred in Germany, the manufacturer or pharmaceutical entrepreneur is a German company and an identical product exists within the purview of the Pharmaceutical Products Act. On the other hand

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[424] Kullmann in: Kullmann/ Pfister, Kza. 3800 at 11.
[425] Kullmann in: Kullmann/ Pfister, Kza. 3800 at 12 referring to BT-Drucksache, 3. Wahlperiode Nr. 654 v. 13.11.1958 at 29.
[426] Sander, *AMG* § 84 para. 9b at 11.
[427] Kullmann in: Kullmann/ Pfister, Kza. 3800 at 12.

a possible damage claim is not affected by the fact that a pharmaceutical product distributed to the consumer within the purview of the Pharmaceutical Products Act, was applied in a foreign country and it was only then that damaging effects occurred.[428]

Subject to compulsory marketing authorisation or is exempted by ordinance from it:

A further condition for liability is that the pharmaceutical product is subject to compulsory marketing authorisation or is exempted by ordinance from it. It is irrelevant in this context, if the pharmaceutical product was in fact authorized by marketing authorization. What is solely decisive is if it is considered to be subject to marketing authorisation, according to the Pharmaceutical Products Act provisions[429].

The liability regulation, § 84 *AMG*, further applies to pharmaceutical products - provided the other conditions are met -, which - even though in general are subject to the marketing authorisation regime - have been exempted by ordinance from compulsory marketing authorisation, according to § 36 *AMG*[430].

2. The claim conditions (*Anspruchsvoraussetzungen*)

a. The general liability conditions, § 84 S. 1 *AMG*

The basic requirements for the obligation to pay damages under § 84 *AMG* are: that as a result of the application or administration of a drug affected by the liability provision, a

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[428] Sander, *AMG*, Erl. § 84, para. 9 b; Kullmann in: Kullmann/ Pfister, Kza. 3800 at 13.
[429] § 21 *AMG*; for conditions also see explanations, above, under II. 3.
[430] § 21 *AMG*; for conditions also see explanations, above, under II. 3.

person is killed, or the body or the health of a person is significantly injured (*nicht unerheblich verlezt*).[431]

Killing, or considerable injury of a person's body or health:

The required consequence, that a person shall have been killed or significantly injured, determines the protective ambit by reference to the object affected. The legal objects protected under § 84 *AMG* - life, body, health - basically follow the concept of § 823 *BGB*, but in contrast to that, § 84 *AMG* only covers damages to persons (*Personenschäden*), not damages to things (*Sachschäden*) or pure economic loss (*reine Vermögensschäden*).[432] Furthermore § 84 *AMG* requires the injury caused to be at least "considerable" to some extent (*nicht unerheblich*), which is not further explained. As a matter of common sense though, the intention is to exclude liability for "trivial or insignificant injuries (*Bagatellschäden*[433]), also called "socially adequate injuries" (*sozialadäquate Verletzungen*"[434]), which basically means injuries where the help of physicians is not necessarily required or where no considerable impairment of the bodily well-being was reported.[435] The term certainly is legally indeterminate and in need of being fleshed out by the exercise of intelligent judgment. In this respect, the injury's

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[431] § 84 S. 1 *AMG*.
[432] Sander, *AMG* § 84 para. 10 at 13; Kullmann in: Kullmann/ Pfister, Kza. 3800 at 17; Deutsch, at 589 para. 881.
[433] Sander, *AMG* § 84 para. 11 at 13f.
[434] Kullmann in: Kullmann/ Pfister, Kza. 3800 at 18; Deutsch, [1979] VersR 685 at 686.
[435] This interpretation is used by the criminal law science, where the term "*nicht unerhebliche Verletzung*" is used in the criminal code in connection with the suspension of a driver's license, in the course of which an objective measure is used and subjective over sensitivity does not fall into account, Kloesel/ Cyran, *AMG* § 84 para. 10 at 104a f.; Kullmann in: Kullmann/ Pfister, Kza. 3800 at 18. Also see Sander, *AMG* §

significance needs to be defined in its quantitative as well as its qualitative perspectives. Here the duration of suffering, the dimension or degree of handicap or impediment, and the intensity of pain inflicted may all be considered.[436]

To put things in perspective, the statutory establishment of risk liability for pharmaceutical products, as a consequential reaction to the tragic events in the "*Contergan*" catastrophe, was intended to provide a sufficient economic security for the victims of unforeseen damages caused by pharmaceutical products. It also was to express the evaluation of interests in favour of the economically weaker consumer, who became a victim of pharmaceutical product injury, as opposed to the interests of the pharmaceutical entrepreneur.[437] This allows the conclusion to be drawn that the liability system centered on § 84 *AMG*, is primarily focused on the alleviation of economic need in case of damages caused by pharmaceuticals[438]. Accordingly, a minor indisposition of "not feeling well", or conditions such as indigestion and minor headaches, or insignificant temporary allergic reactions, are all irrelevant.[439]

As a result of administration:

The person's death or his significant injury must have occurred as a result of the drug's application or administration. This in the first instance requires a causal connection

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84 para. 11 at 13 f., who points out that the term used certainly does not mean that compensation is allowed only in the case of severe injuries, but rather intends to exclude "bagatelle" or trivial damages.

[436] Deutsch, at 589 para. 881.

[437] For this approach for a normative determination of the term "*nicht unerhebliche Verletzung*" see Sander, *AMG* § 84 para. 11 at 13 f.

[438] Sander, *AMG* § 84 para. 11 at 14, therefore is of the opinion, that the term "*nicht unerhebliche Verletzung*" can be set on relatively high.

[439] Kloesel/ Cyran, *AMG* § 84 para. 10 at 104a f.

between the pharmaceutical product's application and the violation of life, body or health, which then caused the damage.[440] The examination of cause basically follows the same rules and attribution or imputation criteria as described for § 823 *BGB*, while similar problems might occur. By way of distinction, though, the question of adequate cause, which refers to the general possibility of foreseeing or predicting the consequences, cannot be used to delimit liability under § 84 *AMG* , because it concerns a regulation imposing risk liability, which already presupposes the realisation of a foreseeable specific danger, namely the pharmaceutical product risk.[441] In this way § 84 *AMG* serves to balance the consequences of the pharmaceutical danger, which was authorised. Therefore it is not a question of causation any more, whether a determined damage event was supposed to have been foreseen due to prior experience. What matters here is only whether it concerns a specific result of those dangers, in view of which the general public was supposed to be indemnified for their losses.[442] This actually refers to the requirement or condition for imposing risk liability, namely that the injury has to be the typical result of the anticipated pharmaceutical product risk.

In other words, besides a pure causal connection there is also required a realisation of the particular pharmaceutical product danger, as a limitation of liability. As a consequence in the frame of determination of causation, it needs to be carefully examined whether the injury or damage caused falls within the ambit of the protection aimed at by § 84 *AMG* (*Schutzzweck der Norm*). That is, if beyond the pure causal connection generally, then the

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[440] For an example see *OLG* Stuttgart [1990] VersR 631 at 633 - "*Impletol*".

[441] Deutsch, [1979] VersR 685 at 689; Deutsch, "*Begrenzung der Haftung aus abstrakter Gefärdung wegen fehlender adäquater Kausalität - Bemerkung zum schadensrechtlichen Aspekt des Urteils des HessVGH v. 16. Nov. 1965*" [1966] Juristischenzeitung 536 at 537; Kullmann in: Kullmann/ Pfister, Kza. 3800 at 590.

restriction of liability to specific cases is required. Here, for example, "as a result of the application" refers to the personal ambit of protection (*persönlicher Schutzbereich*). As a statutory provision for the consumer's protection, § 84 *AMG* limits liability to patients who have actually consumed the product by application or administration. This means that a pre-condition of liability is that the injured person has actually either taken or applied the pharmaceutical product, or that it has been given, injected or otherwise administered to him. Further liability delimitation requirements concerning realisation of the particular danger of pharmaceutical products are described in the special liability conditions in § 84 S. 2 Nr. 1 and Nr. 2 *AMG*. According to Nr. 1, it is a requirement that the injury be caused exclusively by the defectiveness of the drug, which means its harmful qualities. Alternatively as provided by Nr. 2, the injury needs to be solely the result of the missing or defective information provided.

b. The special liability conditions under § 84 S. 2 *AMG*

Even if the general liability conditions of § 84 S. 1 *AMG* are fulfilled, liability is still limited and only imposed in the event that one of the special conditions given in S. 2 Nr. 1 - referring to the defective pharmaceutical product - or Nr. 2 - referring to defective instruction - can also be shown.

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[442] Kullmann, [1981] PharmaRecht 112 at 112; 79 *BGHZ* 259 at 262 f.

aa. Nr. 1: product defect

In conformity with § 84 S. 2 Nr. 1 *AMG*, liability is restricted in several ways and only exists: if the pharmaceutical product, used pursuant to the intended, appropriate and ordinary indicated use (*bestimmungsgemäßem Gebrauch*) has harmful effects, which exceed the bounds considered justifiable or reasonable in the light of knowledge available in medical science and which have their origins in the area of development or manufacture. Even though the term "defect" has not been used in compliance with general terminology, § 84 S. 2 Nr. 1 *AMG* refers to the general product liability categories of development defects, design defects and defects in manufacture[443]. Although the defective product itself is not directly topical to this present thesis, the conditions of liability imposed by § 84 S. 2 Nr. 1 *AMG* have to be noted in order to analyse the whole concept of risk liability for pharmaceutical products, including the provisions of § 84 S. 2 Nr. 2 *AMG* concerning defective instructions, which are the main focus of this thesis. In light of the need to concentrate on this focal point, the requirements of § 84 S. 2 Nr. 1 *AMG* cannot be explained in every detail, but will be considered to the extent necessary and appropriate in relation to that focus, *i.e.*, in the essential fundamentals needed to furnish a reasonable understanding of pharmaceutical risk liability provided by the interplay of § 84 S. 2 Nr. 1 and Nr. 2 *AMG*.

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[443] Deutsch, at 591 para. 886, at 593 para. 891; Udo Wolter, *"Die Haftung des neuen Arzneimittelgesetzes"* [1976] Der Betrieb 2201 at 2004: hereafter cited as DB, with an interesting illustration referring to manufacturing defects in case of pharmaceutical products; that the statutory provision only refers to harmful effects which have their origin in the process of development or manufacture, is probably due to the fact, that pharmaceutical products do not have a technical design in the sense of a construction like other products, Deutsch, [1989] JZ 855 at 855. They rather follow a certain formula, developed from chemical compositions of active agents, which belongs to the process of products development. Therefore, pursuant to general terminology, the circumscription/ paraphrase "in the process or area of development" also comprises what are generally referred to as "design" defects, Prütting & Prütting [1978] DAZ 256 at 258.

(1). Occurrence of harmful effects under appropriate use, pursuant to the intended and ordinary use of the pharmaceutical product

"Harmful effects" (schädliche Wirkungen) of pharmaceutical products means: side-effects[444] and also interaction with other drugs, which have any disadvantageous influence on the pharmaceutical consumer's health.[445]

"Appropriate, pursuant to the intended and ordinary use (*bestimmungsgemäßer Gebrauch*)" is any application or utilisation, covered by the instructions and information provided by the pharmaceutical entrepreneur on the package label, in the package insert, by expert information or in advertisements, as well as through instructions of pharmaceutical company representatives to physicians.[446] This also includes any application, not expressly recommended by the pharmaceutical entrepreneur, but based on generally recognised scientific therapeutic custom as performed in practice, which was not contra-indicated by the pharmaceutical entrepreneur, even though he knew about it or should have known.[447] Such consumer or application customs, which were originally not foreseen by the pharmaceutical entrepreneur but passively accepted or even approved,

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[444] For a definition see § 2 Nr. 13 *AMG*:
"Side effects are those undesired concomitant phenomenons occurring under pursuant to the intended, appropriate and ordinary use (*bestimmungsgemäßem Gebrauch*) of the pharmaceutical product."
[445] Kullmann in: Kullmann/ Pfister, Kza. 3800 at 22.
[446] Sander, *AMG* § 84 para. 13 at 17; Kullmann in: Kullmann/ Pfister, Kza. 3800 at 22.
[447] Sander, *AMG* § 84 para. 13 at 17; Deutsch, at 591 f. para. 885, 887.

occur over and over again.[448] In this case, however, he has the option to exonerate himself by warning about the consequences of: incorrect use, use contrary to the indication or misapplication.[449] This is because the pharmaceutical entrepreneur, who has brought a pharmaceutical product into public circulation, has the opportunity to determine the "ordinary, intended and contemplated use" (*bestimmungsgemäßen Gebrauch*) by way of indication or contra-indication.[450]

Therefore he can considerably reduce his liability risk, if he explicitly specifies the range of application, the highest dosage allowed, the mode of application, any incompatibility with other drugs,[451] an approximate maximum treatment duration and, if he unequivocally designates those persons who, in view of possible harmful side-effects in their case are not to use the product.[452] This shows the close connection between liability under § 84 S. 2 Nr.1 *AMG* and the duty to give instruction or warning.[453] Of course, the pharmaceutical entrepreneur is expected to determine clearly the "*bestimmungsgemäßen Gebrauch*"[454] as such; and also, if necessary, to set out and advise against perceived incorrect uses or use contrary to the indication[455]. In practice this is particularly relevant

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[448] This is not a matter of not obviated foreseeable misuse, as such would clearly not be considered in establishing liability under § 84 S. 2 Nr.1 *AMG*, Kullmann in: Kullmann/ Pfister, Kza. 3800 at 22, footnote 72.

[449] Kloesel/ Cyran, *AMG* § 84 para. 11 at 105.

[450] Deutsch, at 591 f. para. 887; as an example also see reasoning in *OLG* Stuttgart [1990] VersR 631 at 633 - "*Impletol*".

[451] Günter Hager, "*Schäden infolge Unvereinbahrkeit mehrerer Medikamente - Beitrag zurHaftung für Instruktions- und Herstellerfehler*" [1987] VersicherungsRecht 1053 at 1055.

[452] Kullmann in: Kullmann/ Pfister, Kza. 3800 at 22 f.; Deutsch, at 591 f. para. 887.

[453] Wolter, [1976] DB 2001 at 2004.

[454] *E.g.*, "*P must not be taken or applied if XY*" or "*if XY before starting the P-treatment a sufficient XY-therapy must be performed*" or "*treatment with P at the same time as XY must be avoided*", Kullmann in: Kullmann/ Pfister, Kza. 3800 at 23.

[455] This is advisable in view of consumer security, even though it is not mentioned in the § 84 *AMG* text. However, this does not mean that the pharmaceutical entrepreneur is able to escape liability by giving overly careful defensive contra-indications about all kinds of possible negative fields of application, e.g.

in relation to incompatibilities and risks.[456] To restrict validly the "*bestimmungsgemäßen Gebrauch*", he is also required to give understandable information in a readable print and on technical format package inserts - especially in the case of non-prescription drugs - because his liability depends decisively on the consumer's understanding.[457] However, the pharmaceutical entrepreneur can only restrict liability for product-inherent effects by way of instruction, if the harmful effects do not occur despite consideration and observance of that information.[458]

In view of § 84 S. 2 Nr. 1 *AMG*, any form of misuse is considered incorrect use and does not lead to the pharmaceutical entrepreneur's liability. If a pharmaceutical product, for example, only has harmful effects in case of excessive use, liability under the Pharmaceutical Products Act can only exist with regard to § 84 S. 2 Nr. 2 *AMG*.[459] If those special liability conditions are not met, then at best only fault dependent liability under § 823 I *BGB* comes into question.[460] With § 84 *AMG*, the legislator has anticipated the issue of health dangers arising from frequent and substantially incorrect use, and intends to prevent possible damages occurring by way of statutory provision, by making such pharmaceutical products subject to an obligatory doctor's prescription in compliance with § 48 I *AMG*, in connection with § 48 II Nr. 1 b *AMG*.

"*the first month of pregnancy*"; the same is true about recommendations such as "*P should only be taken according to physician's advice*" or "*only with precaution*" or "*P should be resigned*", Deutsch, at 592 para. 887; Kullmann in: Kullmann/ Pfister, Kza. 3800 at 24.

[456] Kullmann in: Kullmann/ Pfister, Kza. 3800 at 23.

[457] Kullmann in: Kullmann/ Pfister, Kza. 3800 at 24.

[458] Sander, *AMG* § 84 para. 15 at 19; this issue will be discussed below with analysis of § 84 S. 2 Nr. 2 *AMG*, referring to instruction defects.

[459] 106 *BGHZ* 273 at 278 ff. - "asthma-spray".

[460] Wolter, [1976] DB at 2004.

(2). Harmful effects exceeding the bounds considered justifiable in light of knowledge available in medical science

Those pharmaceutical products with harmful effects exceeding the bounds considered reasonable, in the light of available medical knowledge, are by definition risk-laden (*bedenkliche*) drugs under § 5 II *AMG*.[461] They are prohibited from being put into public circulation according to § 5 I *AMG*. If they have been marketed nevertheless, liability is appropriately imposed according to § 84 *AMG*.[462] It is not easy to define or determine when exactly harmful effects exceed the bounds considered justifiable in the light of available medical knowledge. The question of medical justifiability[463] (*Vertretbarkeit*) requires a weighing exercise, according to which the therapeutic value of the product preponderates over its harmful effects.[464] To that extent it is presumed, that some harmful side-effects can generally be accepted. It all depends on the therapeutic expectations, and to what extent the side- and interaction-effects are to be tolerated until they overwhelm the therapeutic value and utility (*Nutzen*) of the pharmaceutical product.[465]

The decisive factor is the knowledge (*Erkenntnis*) available in medical science. Even though the medical expert witness has to judge the issue of justifiability, what matters in this estimation is also the patient's acceptance of side-effects.[466] In other words, the

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[461] For the entire statutory wording see above, under II 4.
[462] A corresponding evaluation is found under provisions concerning the procedure of admission for pharmaceuticals: § 25 II Nr. 5 *AMG*, where under the same conditions the marketing authorisation may be refused and like-wise § 30 I *AMG*, pursuant to which the marketing authorisation can be withdrawn or revoked.
[463] Sander, *AMG* § 84 para. 14 at 17 ff.; Kullmann in: Kullmann/ Pfister, Kza. 3800 at 25 ff.
[464] BT-Drucksache 7/3060 at 45.
[465] Deutsch, at 592 para. 888.
[466] Deutsch, at 592 para. 888; *OLG* Stuttgart [1990] VersR 631 at 632 ff. - "*Impletol*".

question is: if they are bearable and can be reasonably expected to be tolerated (*zumutbar*) by the patient.[467] Even then, however, a risk-benefit evaluation needs to be undertaken to determine whether a harmful effect is still justifiable.[468] In this regard an important distinction exists in comparison to the corresponding evaluation, in the context of the procedure for pharmaceutical product admission.

Whereas in relation to the decision about the marketing authorisation, the risk-benefit evaluation is an abstract one, regarding the justifiability or non-precariousness of the pharmaceutical product. In the liability process against the pharmaceutical entrepreneur, on the other hand, it is focused on the administration of the product in the concrete case regarding the particular injured patient.[469] Additionally in this case it needs to be positively determined whether the pharmaceutical product has non-justifiable or dangerous side-effects; whereas during the admission procedure one simply does not fully know as yet what consequences it may produce.[470] Even though the decision is supposed to be based on an objective point of view, which follows out of § 84 S. 2 Nr. 1 *AMG*, turning upon "the light of knowledge available in medical science", this assessment certainly includes the extent, gravity and frequency of experienced side-effects. Above all, it turns their reversibility, as well as any reasonable and plausible alternative methods of treatment, with lesser risk.[471] Examples of the justifiability of harmful effects are:

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[467] Kullmann in: Kullmann/ Pfister, Kza. 3800 at 27.

[468] A detailed explanation of this rather complicated procedure of risk-benefit-evaluation exceeds the purview of this thesis; for a comprehensive overview on this see Kullmann in: Kullmann/ Pfister, Kza. 3800 at 27 ff.

[469] As in apparently *OLG* Stuttgart [1990] VersR 631 at 632 ff. - "*Impletol*".

[470] Kullmann in: Kullmann/ Pfister, Kza. 3800 at 27, footnote 83 a.

[471] Deutsch, at 592 para. 888; Kullmann in: Kullmann/ Pfister, Kza. 3800 at 29. Regarding the consideration of subjective peculiarities of the injured patient see: *OLG* Stuttgart [1990] VersR 631 at 632 f. - "*Impletol*", where the question was, whether the pharmaceutical entrepreneur is also responsible for damages, which

severe side-effects of chemotherapy in case of carcinoma[472], or anaphylactic shock sustained through antibiotics in cases with severe symptoms[473]. Examples for non-justifiability are: impaired vision resulting from headache remedies,[474] malformation in new-borns caused by pregnancy tests,[475] and brain contraction caused by pharmaceuticals against climacteric problems.[476]

(3). The decisive moment for judgment in the risk-benefit evaluation

Ultimately the time of judgment decides whether § 84 S. 2 Nr. 1 *AMG* establishes risk liability or liability based on fault.[477] Opinions in the learned literature dispute the moment which is decisive for the question: whether the harmful effects of a pharmaceutical product exceed the bounds considered justifiable in light of the knowledge available in medical science? Some opinions focus on the standard of knowledge in medical science at the time of distributing the pharmaceutical product.[478] On the other hand the time of the final court hearing has also been suggested.[479] It seems appropriate that preference should be given to a reflection which encompasses both

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only occur through combined action of the pharmaceutical product and subjective peculiarities of the patient; which was answered in the positive concerning the intention and purpose of the Pharmaceutical Product Act.

[472] Deutsch, at 593 para. 888.

[473] Sander, *AMG* § 84 para. 14 at 17 f.

[474] Sander, *AMG* § 84 para. 14 at 17.

[475] Hermann Plagemann, "*Das neue Arzneimittelrecht in der Bewährung - Zur Rechtslage im Duogynon-Fall nach AMG 76*"[1978] Wettbewerb in Recht und Praxis 779 at 781.

[476] *BGH* (Urteil v. 19.3.1991) [1991] VersR at 780 - "*Alival*".

[477] See explanations to § 823 *BGB* above under A., II., 2., d.

[478] Sander, *AMG* § 84 para. 14 at 18; H. Weitnauer, "*Die Produkthaftung für Arzneimittel*" 1979 Pharmazeutische Industrie 425 at 427; hereafter cited as Pharm.Ind.

[479] Deutsch, [1979] VersR 685 at 687; Deutsch, at 593 para. 890; corresponding apparently *OLG* Stuttgart [1990] VersR 631 at 633 - "*Impletol*".

moments, considered above, by way of retrospective. In conformity with this view, the subsequent knowledge, existing at the time of the last court hearing, is to be projected back to the time of distribution.[480] The question then is whether the harmful effects, had they been known, and considering the supply of alternative pharmaceutical products at that time, could have been regarded as acceptable?[481] This allows one to take into account the existing knowledge about harmful qualities and effects of a pharmaceutical product at the time of judgment, especially in regard to the question of reversibility of side-effects in compliance with a newer standard of medical science, which is the most decisive factor of all for judgment on the justifiability of the particular drug.[482] By such a retro-projection of the most current knowledge to the time of distribution, the periphery of pharmaceutical scientific knowledge of that time can be taken into account, for instance the availability of alternative therapy options and their feasibilities (*Einsetzbarkeit*). Such a subsequent prognosis - also referred to as a subsequent liability legal "diagnosis"[483] - probably comes closest to the intention of the legislator, who wanted to provide regulations against a future "*Contergan*" catastrophe with § 84 *AMG*.[484]

(4). Harmful effects laying the foundation in the process (*im Bereich*) of development or manufacture

Under § 84 S. 2 Nr. 1 *AMG*, liability is limited to cases where the harmful effects have their origin in the process of development or manufacture. This means that a particular

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[480] Kullmann in: Kullmann/ Pfister, Kza. 3800 at 33; *OLG* Stuttgart [1990] VersR 631 at 634 - "*Impletol*".
[481] This question corresponds to the one asked in the procedure for the pharmaceutical product's admission, Deutsch, at 593 para. 890; Kullmann in: Kullmann/ Pfister, Kza. 3800 at 33.
[482] Kullmann in: Kullmann/ Pfister, Kza. 3800 at 33.
[483] Deutsch, [1979] VersR 685 at 688.

connection or nexus of danger is required between the pharmaceutical product's development or manufacture and any harmful effects which have caused death or injury to body or health. The statutory intention is to exclude harmful effects caused by circumstances that only arose after distribution,[485] *e.g.*, through faulty storage in pharmacies, hospitals or private homes, or through inappropriate administration by learned intermediaries, such as physicians and nurses. The requirements are met if the harmful pharmaceutical effects are caused by what is commonly referred to as development defects or manufacturing defects.[486] Possible development defects are, *e.g.*, insufficient pharmacology or toxicology, insufficient examination, and disregard or ignorance of contra-indications pointed out in the literature,[487] as well if the drug's formula or recipe[488] development was defective. One would talk about a defect in manufacture if the product's defectiveness arose during the production process, *e.g.*, the drug's composition does not comply with its intended formula or concept regarding quality or quantity, coating or immunisation.[489] Often the appearance (*Anschein - prima facie*) of harmful consequences arising under correct use, done in conformity with instructions, will speak for the fact that the product examination was insufficient.[490]

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[484] Deutsch, at 593 para. 890.
[485] Kullmann in: Kullmann/ Pfister, Kza. 3800 at 32, Deutsch, at 594 para. 893.
[486] See above, under III. 2. b. aa.
[487] Deutsch, at 594 para. 891.
[488] The term "recipe" defect has been used by Kullmann in: Kullmann/ Pfister, Kza. 3800 at 32.
[489] Deutsch, at 594 para. 893.
[490] Deutsch, at 594 para. 891.

(5). No liability for ineffective drugs

Because § 84 S. 2 Nr. 1 *AMG* only provides for pharmaceuticals with "harmful effects", no liability is imposed under the Pharmaceutical Products Act for ineffective drugs, *e.g.*, caused by a defect in manufacture, too small a quantity of an active agent was put into a drug or vaccination;[491] or the recommended dosage was not high enough to stop or ease the sickness.[492] The classic risk liability for pharmaceuticals is seen in the excess of side- and interaction-effects, but not in a failure to address or stop the sickness. This seems unjustified in view of some types of drugs, such as for diagnostic tests, vaccinations and sera.[493] A complete failure of effect is not a risk liability reason under § 84 *AMG*.[494] The ineffectiveness of the product, in spite of the expectation of effectiveness that has been created, only falls within the ambit of promised (*Garantie*) or fault dependent liability.

bb. Nr. 2: instruction defect

Besides the conditions of the first alternative of § 84 S. 2 *AMG*, such as harmful effects arising from a failure in manufacture or development exceeding the bounds considered justifiable, liability might also arise under § 84 S. 2 Nr. 2 *AMG*. In compliance with that, liability only exists if the harm and as a consequence the damage has occurred as a result of labelling, expert information or instruction for use not then complying with the knowledge available in medical science. This refers to the requirements laid down for drugs in §§ 10 ff. *AMG*, concerning necessary product information, instructions for use

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[491] Prütting & Prütting, [1978] DAZ 256 at 258.
[492] Deutsch, [1979] VersR 685 at 686.
[493] Deutsch, at 594 para. 901.
[494] Kullmann in: PharmaRecht 1981, 112 at 116

and warnings. Within this second liability provision, the product liability category of so called instruction defects is embraced, including absent and insufficient warnings. However, liability can only exist where the particular condition is met, that the instruction defect is contained in either the labelling (§ 10 *AMG*), the expert information (§ 11 a *AMG*) or in the the package insert (§ 11 *AMG*). False information or omitted warnings on other occasions or in another context, *e.g.*, in advertisements, do not trigger liability under the second alternative of § 84 S. 2 *AMG*.

Information in labelling, expert information and instruction for use:

Necessary information can be embodied in either the labelling, the expert information or the package insert. According to § 10 *AMG* the labelling requirements are to show *inter alia*: the name, or company name, and the address of the pharmaceutical entrepreneur, the name of the drug, the marketing authorisation number, the batch identification, the pharmaceutical form, the content by weight, volume or number of items[495], the method of administration and the active constituents according to type and quantity[496]. In case of gene-technology manufactured drugs, the active substance and the designation of the micro-organism or the cell line which has been gene-technologically modified during manufacture, must also appear, as well as the expiry date[497]. So, depending on the situation, must the indication "prescription-only" or "pharmacy-only", or, where applicable, the indication "sample-only", the indication "keep out of reach for children",

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[495] As a case example, see: *AG* Lüneburg, confirmed by *OLG* Celle in: Sander, § 10 *AMG* case Nr. 1 at 1 f.
[496] As a case example, see: *AG* Lüneburg, confirmed by *OLG* Celle in: Sander, § 10 *AMG* case Nr. 1 at 1 f.
[497] As a case example, see: *LG* Köln in: Sander, § 10 *AMG* case Nr. 2 at 1 ff..

and as far as necessary, precautionary measures for the disposal of unused drugs. In the package insert or expert information there must additionally be contained information about, *inter alia*: fields of application, contra-indications, side-effects, any interaction with other products, the dosage instructions, the duration of administration , important incompatibilities, measures to be taken in case of emergency, symptoms and antidotes as well as the pharmacological and toxicological properties, indications for the administration to certain groups of patients, and any particular indications for storage and retention, etc.

Instructions for use:

Instructions for use are necessary for achieving the intended administration of the product, for bringing the therapy correctly into effect, and above all for the avoidance of excessive dosage[498]. The idea is to make the pharmaceutical product available to patients and their physicians for particular use in a specifically indicated frame.

Warnings:

Necessary warnings might be given on containers, outer packages, package inserts or expert information. They regularly contain directions not to use the product in particular ways.[499] They are supposed to make the patient aware with the help of his physician[500], that taking the pharmaceutical product is contra-indicated or, as the case may be, that at

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[498] As a case example, see 106 *BGHZ* 273 at 278 ff..
[499] Deutsch, at 596 para. 900.

least another pharmaceutical product needs to be discontinued because of possibly harmful interactions. In this way it has been considered enough that the physician has warned the patient about the dangers. The pharmaceutical entrepreneur does not need to do so as well.[501] This principle is called the doctrine of the "learned intermediary rule" in Anglo-American jurisprudence.[502]

(1). Labelling, expert information or instruction for use complying with the knowledge then available in medical science

Within the purview of liability under § 84 S. Nr. 2 *AMG*, liability is restricted to instruction defects that do not comply with the knowledge available in medical science. In contrast to liability under § 823 *BGB*, the focus here is not on the presupposed ability of respective consumers to recognise and understand the meaning, but objectively on the knowledge available in medical science. What is decisive in this context is therefore not the question, whether the information provided in the package insert was generally understandable, *i.e.*, in view of the patient's education and previous experience.

However, it is essential to define, what the statutory provision is supposed to convey with the term "in compliance with knowledge available in medical science". As a complement to § 84 S. 2 Nr. 1 *AMG*, the legislator with § 84 S. 2 Nr. 2 *AMG* intended to establish a damage compensation claim in cases where a pharmaceutical product can be applied in

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[500] *LG* Hamburg in: Sander, § 11 *AMG* case Nr. 1 at 2, although referring to the required information under § 11 I *AMG* in general and not to warnings only.

[501] This view however has not yet been manifested by the case law. *Vice versa*, the package insert information does not substitute for the physician's duty to give full disclosure to the patient, *LG* Stuttgart in: Sander, § 11 *AMG* case Nr. 6 at 6 ff.

[502] Deutsch, at 596 para. 900 referring to *Raves v. Ortho Pharmaceutical Co.* 567 F.Supp. 1287 (1991).

such a way that no medically unjustified harm or damage will be caused, namely when used in compliance with the knowledge available in medical science at that time. However, liability shall be imposed where this possibility is frustrated, because those precautionary measures which turned out to be necessary, in conformity with scientific examination of the remedy product, have not been explained by the pharmaceutical entrepreneur.

Consequently, liability under § 84 S. 2 Nr. 2 *AMG* is imposed in cases where such information or warning about dangers recognised in medical science has not been provided in the labelling, the package insert[503] or expert information[504], and therefore did not in a legally valid way restrict the appropriate, ordinary and indicated use in compliance with the medical knowledge available[505].[506]

However, as a manifestation of defensive pharmacology, sometimes scientifically unjustified warnings are given, *e.g.*, against the drug's administration during pregnancy. Such warnings do not necessarily comply with the knowledge of medical science available at that time. Rather they are considered as excess warnings. If a patient consequently does not receive the drug, of course risk liability cannot be applied because the pharmaceutical product was not administered. Nevertheless, liability dependent on

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[503] *LG* Hamburg in: Sander, § 11 *AMG* case Nr. 1 at 2 ff. about additional information in package inserts (§ 11 V S. 2 *AMG*), which considerably depreciated the required patient information given in compliance with § 11 I *AMG*; also *LG* Düsseldorf in: Sander, § 11 *AMG* case Nr. 5 at 5 ff.; regarding inadmissible advertisements in package inserts see: *LG* Hamburg in: Sander, § 11 *AMG* case Nr. 4 at 4 ff.; concerning the relation or distinction between package inserts and advertisements see: *OLG* Köln in: Sander, § 11 *AMG* case Nr. 3 at 2 ff.

[504] *OLG* Frankfurt [1995] NJW-RR 406 at 408 - "mumps-vaccination" ("*Mumps-Schutzimpfung*"); Hans Josef Kullmann, "*Die Haftungsregelung des § 84 AMG*" [1981] PharmaRecht 112 at 116.

[505] *OLG* Stuttgart [1990] VersR 631 at 633 f. - "*Impletol*".

fault under § 823 I *BGB* might be imposed, on the theory that a necessary treatment was omitted for no justifiable reason, as mentioned above.

The requirements for labelling or user instruction are not met if the statutorily described conditions in §§ 10 ff. *AMG* are not satisfied[507], so that the recognised dangers cannot be avoided. This is especially so if those warnings or storage and retention indications, necessary according to current medical information, are in any way deficient or absent.[508] The same is true, *e.g.*, about missing expert information according to § 11 a I Nr. 14 *AMG*, which refers generically to "other necessary indications". Such might be any possible information considered to be necessary over and above that already given in conformity with those matters anticipated in the enumeration of §§ 10 and 11 *AMG*, for labelling and package inserts. An example might be special indications for administration to certain groups of patients.[509]

This final catch-all provision specifies that case constellations, such as experienced in the "*Estil*" case, are supposed to be encompassed in the liability regulations. At that time, it will be remembered, the package insert under the paragraph for contra-indications only contained the sentence that "*intra-arterial injection must be avoided with certainty*". No reference was made to the particular consequences, namely that a mis-performed application of the injection would almost definitely result in a arm amputation. Also, at least in the first instance, no indication had been given regarding the fact that the general

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[506] This condition was found not to be met in: *OLG* Frankfurt [1995] NJW-RR 406 at 408 - "mumps-vaccination".
[507] *AG* Lüneburg, confirmed by *OLG* Celle in: Sander, § 10 *AMG* case Nr. 1 at 1 f.; *OlG* Köln in: Sander, § 10 *AMG* case Nr. 2 at 1 ff..
[508] 106 *BGHZ* 273 at 278 ff.

practice of performing injections into the bend of the arm needed to be avoided because specific anatomic circumstances created a considerably enlarged danger of a mis-application, as science had recently proved.[510]

While these findings, contemplated in the "*Estil*" case, were based on the delict law provision of § 823 I *BGB*, the Federal Supreme Court basically confirmed these legal issues with reference to § 84 S. 2 Nr. 2 *AMG* on the occasion of the *"Alupent Dosier-Aerosol"* asthma spray decision. In this case the patient died in the course of an asthma attack, during which he had made excessive use of the defendant's asthma spray.[511] With this decision the Federal Supreme Court for the first time gave its comprehensive opinion on pharmaceutical product liability for instruction defects, based on § 84 S. 2 Nr. 2 *AMG*.[512] The Court stated that the pharmaceutical entrepreneur does not meet his obligation to provide the necessary instructions for use, complying with the current medical knowledge, if he confines them to the obligatory information as statutorily directed in §§ 10 ff. *AMG*. This means, that the duty to inform and warn about pharmaceutical risks does not only exist in relation to possible side-effects, but also with regard to possible dangers that might occur, due to forms of misapplication such as over dosage in a life threatening situation. With this the Court made clear that the duty to warn is also extended to forms of misuse that can be anticipated and expected, as long as they do not have to be considered unreasonable. The Court also pointed out, that the duty to warn under the Pharmaceutical Products Act is not restricted to cases where warnings

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[509] Prütting & Prütting [1978] DAZ 256 at 258.
[510] *BGH* NJW 1972, 2217 at 2220 - "*Estil*".
[511] See under A, IV, 2., b., aa.
[512] Deutsch, [1989] JZ 855 at 855.

were directed by the competent higher federal authority by imposition,[513] or requested by ordinance;[514] moreover, the duty exists independently and in addition to those.[515] If the occasion calls for it, warnings even have to be given in addition to the necessary instructions for use if, on the grounds of research and examination, documents or other circumstances, or experience which has come to light, the self-suggested assumption exists that the consumer might suffer health injuries without such references.[516]

Because user instructions or package inserts frequently remain unread, like any other kind of "fine print", this is required to provide clear and striking information and warnings where the situation calls for it. If a possibility of misuse in dramatic situations is likely to exist,[517] or a specific danger has already materialised frequently,[518] then a warning required in a prominent spot where it is easy to read, if possible right on the outer package.

Special legal problems that have been contemplated in this context concern the question, whether expert information or package inserts comply with the knowledge available in medical science, even when they contain no false information but omit particular matters recognised by more recent scientific knowledge?

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[513] (*durch Auflage angeordnet*), § 28 II Nr.1 and Nr. 2 *AMG*.
[514] (*durch Rechtsverordnung vorgeschrieben*), § 12 I Nr. 3 *AMG* and § 36 I *AMG*.
[515] The duty of care sometimes requires from the person obligated more than statutory provisions or public authorities require from him, Kullmann [1999] NJW 96 at 98.
[516] A comprehensive overview of the Court's reasoning has been given under A, IV, 2. b., bb.
[517] 106 *BGHZ* at 273 ff. - "asthma-spray".
[518] *BGH* [1972] NJW at 2217 ff. -"*Estil*"; *OLG* Stuttgart [1990] VersR at 631 ff. "*Impletol*"; as negative examples also see Deutsch, at 598 para. 904 referring to *Ashman v. SK&F Lab Company* 702 F.Supp. 1401 (1988); *Franz. Kassationshof v. 8.4.1986 J.C.P.* 1986 II 20721.

One question that occasionally arises in this connection is whether those dangers necessarily must be pointed out when, according to the present standard of medical science, they are considered to be largely known? In this instance only a small percentage of physicians, or some patients taking the drug without previously consulting an expert opinion, would not know about the harmful effects.[519] The scholarly literature has pointed out that it seems to be extremely questionable to not impose liability in such cases, because it has to be further taken into account that a physician's knowledge does not always comply with the prevailing standard of their science. Also, one has to consider the fact that even prescription drugs are frequently kept in family households and occasionally will be taken by persons for whom they were not prescribed. Consumers in such cases would not be protected at all.[520]

Another question frequently arising with regard to § 84 S. 2 Nr. 2 *AMG* in this context is, whether liability can be imposed in cases where dangers that are generally known have been withheld, but only those which, if they had been named, would have been accepted as medically justifiable upon a consideration of the risk-benefit-evaluation? Consequently, would not have resulted in liability compensation in view of the first alternative in § 84 S. 2 *AMG*. On a proper construction of the statutory wording of the second alternative, this question has to be answered in the affirmative.[521]

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[519] Kullmann in: Kullmann/ Pfister, Kza. 3800 at 36.
[520] Kullmann in: Kullmann/ Pfister, Kza. 3800 at 37.
[521] Kullmann in: Kullmann/ Pfister, Kza. 3800 at 37 asserts the question, that this interpretation of the statutory wording might not necessarily comply with the legislator's actual intention. In this connection he refers to the official legislative reasons regarding the Pharmaceutical Product Act, quoting as follows: "Contrary to Nr. 1 an expressive mentioning that this damage is not medically justifiable was not necessary, as the harmful effects addressed by Nr. 2 are always avoidable and therefore medically not justifiable". The

Both alternatives follow a different purpose. While the obligation to compensate for damages under the first alternative exists for injuries or death caused by harmful effects which are not medically justifiable, the second alternative provides for cases where proper information or warning has not been given about existing dangers, in compliance with the medical knowledge then available, independently from the question whether those dangers were medically justifiable under the first alternative.

Therefore the legislator's considered choice of language leads to the consequence that in special situations the patient might be eligible for compensation for side-effects of pharmaceutical products considered as medically justifiable, because the pharmaceutical entrepreneur is open to the accusation that he did not refer to these matters. Even though this might appear peculiar, the second alternative of § 84 S. 2 *AMG* actually only seems to make real sense with this interpretation in conformity with the statutory wording. Otherwise in almost all other cases applicable under this liability provision, the conditions of fault-dependent liability under § 823 *BGB* would have also been met. The

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herewith expressed legislator's opinion, proceeding on the assumption that a damage caused by an instruction defect relevant under § 84 S. 2 Nr. 2 *AMG* would always have been avoidable and therefore medically not justifiable, is referred to as an error by Kullmann. He explains this opinion by reasoning that, particularly in the case constellation referred to, generally no alternative treatment methods would exist, which could have avoided the damage, unless the patient would have declined taking the product at all; see also Kullmann, [1981] PharmaRecht 112 at 117.

With respect, in my opinion this error can be solved by a slightly different interpretation of the legislator's fiat, which entirely corresponds with the actual statutory wording. "Medically not justifiable" in view of § 84 S. 2 Nr. 2 *AMG* - referring to the official statutory reasons - means not justifiable, because the consumer was supposed to be, and could have been, fully informed about the dangers known to medical science and which were acceptable according to the risk-benefit-evaluation, but he was nevertheless left in the dark. In this respect the "avoidable damage" can be seen in the patient's possibility not to take the drug at all, considering the dangers that have been brought to his attention. In view of § 84 S. 2 Nr. 1 *AMG*, "medically not justifiable" means not justifiable because of the knowledge available in medical science and not acceptable according to the risk-benefit evaluation. Therefore the pharmaceutical is not supposed to be put into public circulation. The whole idea of the liability provision under § 84 S. 2 Nr. 2 *AMG* is to ensure the consumer's protection in view of those dangers and any other information concerning the product, judged to be acceptable under the risk-benefit evaluation. Therefore it should always lead to the disadvantage of the

legally responsible pharmaceutical entrepreneur generally can be considered to have violated his delict duty of care if a package labelling or instruction for use does not meet the required standard imposed by the knowledge available in medical science.[522]

(2). The decisive moment or time for the knowledge available in medical science

Required information must follow the most recent standard in medical science.[523] What is decisive is not the time of the product's first distribution but the standard of recognition when the product itself was put onto the market. This means: according to general opinion at the time of distributing the batch or the particular drug in question.[524] If the product has already been put into public circulation at the time when new medical recognition arises, the pharmaceutical entrepreneur subsequently has to take measures to ensure communication of necessary warnings up to the product's expiry date, or recall it.[525] In this way the pharmaceutical entrepreneur is only obligated to give information when the occasion calls for it.[526] This is especially the case if the product turns out to have harmful effects or the prospects of such have been recognised in medical science.[527]

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pharmaceutical entrepreneur, if he does not refer to all the information available. Only then the patient will be in a position to make a reasonable decision about, if anything at all, what should happen to his body.

[522] Kullmann in: Kullmann/ Pfister, Kza. 3800 at 37 f.

[523] *OLG* Frankfurt [1995] RR-NJW 406 at 408 reasoning, that the most recent recognition (at the time of distribution) needs to be considered; Deutsch, [1989] JZ 855 at 856.

[524] Deutsch, at 596 f. para. 902; Kullmann in: Kullmann/ Pfister, Kza. 3800 at 39 referring to 106 *BGHZ* 273 at 282 - "asthma-spray"; *OLG* Celle [1983] VersR 1143 at 1144 - 'Tbc-vaccination".

[525] Deutsch, [1989] JZ 855 at 856.

[526] Denied in *OLG* Celle [1983] VersR 1143 at 1144 -"Tbc-vaccination", because it could not be determined that the information given in the package insert did not correspond with the knowledge available in medical science at the time of the product' distribution, as a case comparable to complications in the plaintiff's case that had not been known of. Therefore the Court proceeded on the assumption that the side effects and risks of the vaccination had been sufficiently described in the package insert.

[527] Denied in *OLG* Frankfurt [1995] NJW-RR 406 at 408 - "mumps" vaccination, because until the plaintiff's incident, no recognition in medical science existed about the circumstance that a mumps

Only under the circumstance that the injury inflicted was caused by harmful side effects known at the time of product distribution, does the damage fall within the protective ambit of § 84 S. 2 Nr. 2 *AMG*.[528] Being strict about this, the information liability under § 84 S. 2 Nr. 2 *AMG* moves closest to the vicinity of fault liability and is actually only a somewhat further developed, objectified liability for a course of conduct contrary to the required level of care.[529] Whoever puts his products onto the market without supplying the necessary information does not meet the required objective "external" duty of care, which allows a conclusion regarding the violation of the subjective "internal" duty of care.[530]

(3). Harm inflicted as a result of information defects; causation and connection of imputation

The damage needs to occur as a consequence of the defective information given[531], *i.e.*, it is not enough to furnish only a causal connection between the product's administration and the violation of interests. This requirement is not met if the patient, *e.g.*, would have taken the drug despite hypothetically having received sufficient information, or otherwise

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vaccination might be considered as a triggering factor for a latent preexisting sickness with diabetes mellitus.

[528] Denied in *OLG* Köln [1994] NJW-RR 91 at 92 - "*insect repellent*", because the symptoms occurred in the plaintiff's case were found not to be corresponding to those side effects, which had been known until this incidence. The Court held that damages which did not need to be referred to according to the knowledge available in medical science would not be included in the protective ambit of § 84 S. 2 Nr. 2 *AMG*.

[529] Kullmann in: Kullmann/ Pfister, Kza. 3800 at 39; Deutsch talks about the synchronizing (*Gleichlauf*) of instruction liability under § 823 I *BGB* and § 84 *AMG*, [1989] JZ 855 at 856.

[530] Deutsch, at 597 para. 903 with further references.

[531] Denied in: *OLG* Celle [1983] VersR 1143 at 1144 - "*Tbc*" -*vaccination*, on the grounds, that it remained doubtful, if the damage occurred as a result of the instruction defect, because an immune defect on his part was also considered as a probable other cause for the complications which occurred in the plaintiff's case. In my opinion this leaves out consideration of the possibility that, if due to a sufficient warning the "*Tbc*" -

would have had it administered anyway, which means under the same conditions which led to the damage, such as too high or low a dosage.[532] The same applies if it is determined that the physician, who treated the patient with the product would not have taken notice of a hypothetical user or expert information embodying the appropriate information.[533]

(4). Ineffective drugs

Contrary to the liability provision of § 84 S. 2 Nr. 1 *AMG*, liability for ineffective drugs might be considered under § 84 S. 2 Nr. 2 *AMG*, because of its different protective ambits. The liability condition that the damage must have occurred as a consequence of pharmaceutical product information not complying with the knowledge then available in medical science, can also be met if a pharmaceutical product, under appropriate and ordinarily intended use, is simply ineffective or inadequate to its function. Thus the liability conditions may be met if, for example, in regard to a particular health condition the dosage is indicated too low in the package insert, even though, based on scientific experience with the pharmaceutical product, a higher dosage has been already proved to be necessary for that condition especially if because of this defective instruction, the patient suffers more severe injury or death. The same is true if it was not indicated that the product, if used in combination with a particular food or other consumer product, is

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vaccination had been omitted, consequentially the injury and as a result the damage would not have occurred.

[532] Kullmann in: Kullmann/ Pfister, Kza. 3800 at 38.

[533] *BGH* [1990] VersR 631 at 633 f. - "*Impletol*".

useless or only slightly effective; and just because of that, the patient's death occurs or he suffers from severe pain for a longer time, or has to endure the fear of death.[534]

3. The opponent of a claim (*Anspruchsgegener*)

The legal obligation according to § 84 *AMG* attaches to the "pharmaceutical entrepreneur" who has brought the pharmaceutical product into public circulation within the purview of the Pharmaceutical Products Act. Therefore he is the claim opponent, consequently the one against whom the claim has to be brought.

a. The "pharmaceutical entrepreneur" bringing the pharmaceutical product into public circulation within the purview of the law

According to the definition given in § 4 XVIII *AMG*, the "pharmaceutical entrepreneur" is any person placing drugs under his own name on the market. Therefore, for the purpose of liability under § 84 *AMG*, it is not important who actually manufactures the pharmaceutical product. This distinction, between product manufacturing and product distribution, is an innovation in the product liability discussion because under German delict law it is generally only the manufacturer who can be brought to account for damage compensation. Strictly speaking, the pharmaceutical product liability is not a manufacturer's liability in the classical meaning of that term.[535] The manufacturer is only the pharmaceutical entrepreneur if he has placed the product on the market under his

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[534] Kullmann in: Kullmann/ Pfister, Kza. 3800 at 38; Kullmann, 196 at 200.
[535] Sander, *AMG* § 84 para. 6 at 7f.

name. If it is a different person who does so, such as a wholesaler, an importer or a pharmacist, the latter assumes the identity of the pharmaceutical entrepreneur.
This is generally independent of the fact that a marketing authorisation for that particular product was granted to him. A person is a pharmaceutical entrepreneur under civil law and thus responsible for a pharmaceutical product, even if he or she brings the pharmaceutical product into public circulation without a marketing authorisation.[536]

§ 4 XVII *AMG* defines "marketing" or "putting a pharmaceutical product into public circulation". In contrast to ordinary language and other provisions enacted for consumer protection, § 4 XVII *AMG* not only sees keeping and offering for sale and distribution as "marketing" or "distributing", but also the keeping in stock for sale or for other forms of supply. With that the Pharmaceutical Products Act draws the line, for any conduct considered as "marketing" or "distributing", far earlier than actual distribution as understood in general linguistic usage.[537]

The term contains a subjective component, namely keeping in stock with the intention of supplying the product to the consumer.[538] This excludes from the ambit of liability, cases where, *e.g.*, the pharmaceutical product was stolen before its entrepreneur actually kept it in stock with the intention for distribution.[539] If a pharmaceutical product is distributed against the will of the person who identified himself with it by his name, he does not

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[536] *BGH* NJW 1990, 2931 at 2932.
[537] Kullmann in: Kullmann/ Pfister, Kza. 3800 at 40.
[538] Sander, *AMG* § 84 para. 7 at 8 f.
[539] Kullmann in: Kullmann/ Pfister, Kza. 3800 at 41. For further examples such as imports, see Kullmann in: Kullmann/ Pfister, Kza. 3800 at 41 f.

become the pharmaceutical entrepreneur and cannot be the object of claim under § 84 *AMG*.[540]

b. The "pharmaceutical entrepreneur" who assumes liability obligations in special cases

aa. Pharmacists as the pharmaceutical entrepreneur

In conformity with the Pharmaceutical Products Act, liability for the pharmacist is not considered because the pharmacist does not distribute the pharmaceutical product himself for the first time under his name. Therefore the entire range of finished drugs (§ 4 I *AMG*) is excluded in this context.[541] The pharmacist's liability under § 84 *AMG* is also excluded as far as marketing authorisation-free pharmaceuticals are concerned, *e.g.*, notably in the ambit of individual prescriptions.[542]

(1). Drug production in pharmacy

The situation is different in cases where the pharmacist himself produces pharmaceutical products which are, as finished drugs, in need of marketing authorisation (§ 21 I *AMG*) or affected by the exemption in the case of standard authorisation (§ 36 I *AMG*) in advance and packages them for first distribution by himself. In this case he is fully exposed to the liability regulation of § 84 *AMG*, unless he restricts production to drugs which "as a result of provable frequent medical prescriptions are produced .....in his pharmacy in batch

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[540] The only imaginable liability would be delict law liability, based on the breach of the duty of care to secure the pharmaceutical product, Sander, *AMG* § 84 para. 7 at 8 f.
[541] Prütting & Prütting [1978] DAZ 256 at 259.
[542] Prütting & Prütting, *ibid.*

sizes up to a maximum of one hundred ready packaged per day" (§ 21 II Nr. 1 *AMG*). Here, the pharmacist is released from obtaining a marketing authorisation and from any liability and duty under § 84 *AMG*. This marks out for the pharmacist the exact borderline of his position as a possibly liable pharmaceutical entrepreneur.[543]

(2). "Non genuine" house specialties

"Non genuine" house specialties are pharmaceutical products produced by an industrial manufacturer in the same composition for several pharmacies, which then, generally under their own name, distribute the products to consumers.[544] Under those circumstances the pharmacist becomes the pharmaceutical entrepreneur and is then responsible under § 84 *AMG*, and in a liability claim is the appropriate defendant.[545]

bb. Anonymous distribution or distribution under a false name

Anonymous distribution of pharmaceutical products, or distribution under false identification, violates the provision of § 9 *AMG*[546] with the consequence that neither party who might be considered responsible can be considered the pharmaceutical

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[543] Prütting & Prütting, *ibid.*

[544] Sander, *AMG* § 84 para. 6 at 7 f. This is often practiced, *e.g.*, with vitamin C products purchasable in pharmacies.

[545] Prütting & Prütting [1978] DAZ 256 at 259; however, many pharmacies also arrange for the manufacturer's name being put on the product with the intention of also including them in the liability regulation of § 84 *AMG*. This however is not always the case, if the inscription, identifies the pharmaceutical producer as only the manufacturer Kullmann in: Kullmann/ Pfister, Kza. 3800 at 43; of the contrary opinion though obviously, Sander, *AMG* § 84 para. 6 at 7 f.

[546] § 9 I *AMG* provides:

"Drugs which are placed on the market within the purview of this law shall bear the name or the company and the address of the pharmacutical entrepreneur."

entrepreneur in the sense required for § 84 *AMG*.[547] In the scholarly literature, some want to apply the liability regulations accordingly, by way of analogy.[548]

4. Burden of proof related questions

As already discussed under explanations of the delict product liability law under § 823 *BGB*, in German law anyone who brings a claim to court has to prove the factual circumstances of his assertion in the event that the defendant disputes them. Consequently the injured plaintiff who bases his claim on § 84 *AMG* has to prove every single factual condition, the existence of which has been disputed by the defendant pharmaceutical entrepreneur.[549]

a. Proof of general liability conditions, § 84 S. 1 *AMG*

With regard to general liability conditions, in case of doubt the injured party has to prove the factual circumstances showing a significant ("not inconsiderable") violation of his interests as protected under § 84 S. 1 *AMG*, as well as the causal connection between that and the administration[550] of a pharmaceutical product put into public circulation by the pharmaceutical entrepreneur. Further, should the occasion arise, the plaintiff has to furnish facts from which it can be deduced that the product is actually affected by the statutory liability provision, namely that the drug is intended for human use and was distributed to the consumer within the purview of the Pharmaceutical Products Act.

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[547] Kullmann in: Kullmann/ Pfister, Kza. 3800 at 43.
[548] Sander, *AMG* § 84 para. 8 at 9 f.; Weitnauer, [1978] Pharm.Ind. 425 at 428.
[549] Kullmann in: Kullmann/ Pfister, Kza. 3800 at 43.
[550] This proof was found not to be furnished in: *OLG* Stuttgart [1990] VersR 631 at 634 - "*Impletol*".

b. Proof of special liability conditions § 84 S. 2 *AMG*

Furthermore the injured plaintiff has to prove that one of the special conditions required in § 84 S. 2 *AMG* are met, if the defendant entrepreneur challenges it.[551]

aa. § 84 S. 2 Nr. 1 *AMG*

In relation to § 84 S. 2 Nr. 1 *AMG*, the plaintiff has to prove that the pharmaceutical product, under appropriate, ordinary use in compliance with the intended use, had harmful effects which exceeded the bounds considered justifiable in the light of knowledge available in medical science.[552] Generally the proof of these special liability conditions, required under § 84 S. 2 Nr. 1 *AMG*, will only be available with the help of an expert witness's opinion, which makes the damage claim procedure a more risky one for the plaintiff.[553]

By further reducing liability for compensation of damages to cases where harmful effects originate in the process of development or manufacture, the statutory regulation requires the plaintiff to prove - just as in product liability cases based on delict law - that the

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[551] Due to major difficulties arising in this context, a reform of the Pharmaceutical Product Act by reversing the burden of proof in favour of the plaintiff has been under political discussion for a long time, which will be explained below.

[552] In this way it has been held that the plaintiff does not have to prove that he himself administered the drug appropriately, Kullmann in: Kullmann/ Pfister, Kza. 3800 at 44. In my opinion this view might be justified on the ground that § 84 S. 2 Nr. 1 *AMG* provides for an objective risk liability. That means, if the plaintiff can prove that the pharmaceutical product has harmful effects under appropriate and ordinary use, in compliance with the intended use, the pharmaceutical entrepreneur's liability is not dependent on subjective components like, for example, the appropriate use in the plaintiff's particular situation. Of the same opinion apparently are Prütting & Prütting [1978] DAZ 256 at 258 under V. Nr. 3 and Nr. 4.

[553] Kullmann, [1978] BB 175 at 177.

pharmaceutical product was already defective when put into public circulation, which means that the harmful effects are not due to facts that arose right after the manufacturing procedure.

bb. § 84 S. 2 Nr. 2 *AMG*

In relation to § 84 S. 2 Nr. 2 *AMG*, the plaintiff for his part has to furnish proof that the labelling, the expert information or the instructions for use did not comply with the knowledge of medical science available at that time.[554] This will probably also require an expert witness's opinion. Additionally he has to prove that the damage occurred as a result of the instruction defect, *i.e.*, that the damage would not have occurred if the instructions had been given appropriately. This proof must satisfy the court that the pharmaceutical entrepreneur's conduct, had it been in conformity with the required duty, would have certainly avoided the damage; the mere possibility, or even a measure of probability, is not enough in this context, as explained generally for delict product liability law[555].

c. Alleviating mechanisms for proof

The Pharmaceutical Products Act does not provide for any possible alleviating mechanisms for furnishing proof in relation to the factual conditions required.

On the occasion of the fifth law amending the Pharmaceutical Products Act, the amendment of § 84 *AMG*, easing the burden of proof situation in favor of the plaintiff,

had already been under political discussion.[556] The suggestion was basically to alleviate the proof of the causal connection between the drug administration and the violation of the plaintiff's interests, by considering it sufficient if the plaintiff was able to furnish enough evidence for a "well-founded suspicion" that the violation of his interest, protected under § 84 S. 1 *AMG*, had occurred as a result of the drug's application. Also suggested was reversing the burden of proof required under § 84 S. 2 *AMG*, by putting it on the defendant. Regarding Nr. 1, the defendant would have to show that the pharmaceutical product "does not have" harmful effects under correct, ordinary and appropriate use, complying with the intended usage, which exceed the bounds considered justifiable in the light of knowledge then available in medical science and as originating in the process of development or manufacture. Similarly in relation to Nr. 2, the defendant would have to show that the damage would have occurred, "even though" a labelling, expert information or user instruction, complying with the knowledge available in medical science, had been provided. However, these suggested changes did not become law. Recently the eighth amending law has passed the legislature and again the establishment of an alleviating mechanism in favor of the plaintiff was debated[557], but not realised.

Therefore one has to consider whether those alleviating mechanisms generally available in damage compensation claims in favor of the plaintiff might be applicable in this context as well. The courts have not yet established a recognisable, standardised and

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[554] Concerning the burden of showing or submitting corresponding facts (which generally complies with the burden of proof) the claim was dismissed in: *OLG* Celle [1983] VersR 1143 at 1144.
[555] See under A, IV, 4., a.; *BGH* [1975] BB 1031 at 1032 with further references.
[556] BR-Drucksache 565/93 v. 13 August 1993 at 25 f..

comprehensive body of doctrine on this issue and scholars have taken different views. Therefore the legal situation can only be explained by showing the anticipated possible alleviating mechanisms which might become applicable.

aa. For proof of a causal connection between administration of the pharmaceutical product and the violated interests: § 84 S. 1 *AMG*

The often difficult proof of causation is eased by the *prima-facie* evidence rule.[558] Accordingly, the appearance of causation based on a typical course of events is enough to serve as a provisional proof. It can be rebutted (*erschüttert*) by another seriously probable or untypical course of events, amounting to more than a merely theoretical possibility.[559] In this context, often it might not be easy to distinguish between the fateful course of a sickness and the altering influence of a pharmaceutical product. Therefore, a lot of possible claims against the pharmaceutical entrepreneur might be dismissed on the level of causation, especially regarding side- and inter-action effects, which are rooted in the developing symptoms of an illness.[560]

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[557] BT-Drucksache 13/10019 v. 4 March 1998 at 2.
[558] Deutsch, at 590 f. para. 884; Kloesel/ Cyran, *AMG* § 84 para. 14 at 105.
[559] Kloesel/ Cyran, *AMG* § 84 para. 14 at 105; see also explanations on the burden of proof of causation under A., II., 6.
[560] Deutsch, at 591 para. 884.

bb. For proof that the pharmaceutical product has harmful effects under appropriate, ordinary and contemplated use: § 84 S. 2 Nr. 1 *AMG*

The proof, that the pharmaceutical product has harmful effects under appropriate, ordinary and contemplated use can occasionally be submitted, like the proof of defectiveness in the context of delict law liability, with the help of the *prima-facie* evidence rule.[561] This is, however, only applicable when there is a typical course of events, *i.e.*, in cases where upon reflection on general life experience or medical knowledge a conclusion can be drawn attributing the damage to a specific cause: namely to the existence of harmful effects in the pharmaceutical product, or *vice versa* from a particular cause a specific sequence of events and damage can be concluded.[562] A corresponding principle of experience will only be allowed if, after the use of a particular batch of a pharmaceutical product in different consumers, the same or similar injuries occur.[563]

According to the jurisprudence of the Federal Supreme Court it might be enough, if several so called "evidentiary signs" (*Beweiszeichen*) speak for the defectiveness of the product.[564]

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[561] Kloesel/ Cyran, *AMG* § 84 para. 14 at 105; Kullmann in: Kullmann/ Pfister, Kza. 3800 at 45.
[562] *OLG* Celle [1983] VersR 1143 at 1144.
[563] Kullmann in: Kullmann/ Pfister, Kza. 3800 at 46 with reference to *BGH* BB 1987 at 295.
[564] *BGH* [1970] BB 1970 at 1414 ff. -brakes -; *BGH* [1973] BB at 1372 ff. - "fireworks".

cc. For proof of a causal connection between the defective pharmaceutical product, according to § 84 S. 2 Nr. 1 *AMG*, and the violated interest

Similarly, in many cases of proof of a causal connection between the defective pharmaceutical product and the violated interest, the principle of *prima-facie* evidence will be applicable.[565] It is probably safe to assume that regularly a general proposition of life experience speaks for the fact that, if a pharmaceutical product under appropriate, ordinary and contemplated use - which already needed to be proved - has harmful effects, then so too the injuries experienced in the injured patient's case - provided they are of the same nature as the typically occurring damages - can be imputed to the administration of the pharmaceutical product.[566]

It is then on the pharmaceutical entrepreneur to submit facts which are sufficient to raise a serious possibility of another course of events sufficient to rebut (*erschüttern*) the *prima facie* evidence. In that case the injured patient has to provide the full proof.

Some scholars are of the opinion that further alleviating mechanisms concerning the proof of causation in this context are not available.[567] They also express doubt if a reversal of the burden of proof can be possibly assumed in cases where a severe design or manufacturing defect has been proved. They reason that the risk liability established by § 84 *AMG* was intended to be some kind of social liability, imposed on the pharmaceutical entrepreneur essentially for such products for which fault could not be proved.[568]

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[565] *BGH* [1970] BB 1970 at 1414 ff.; Kullmann in: Kullmann/ Pfister, Kza. 3800 at 46.
[566] Kloesel/ Cyran, *AMG* § 84 para. 14 at 105.
[567] Kullmann in: Kullmann/ Pfister, Kza. 3800 at 46; Deutsch, [1979] VersR 685 at 689.
[568] BT-Drucksache 7/ 3036 v. 7.1.1975 at 43.

Following this, it was held that if the risk liability provided at the same time includes cases in which fault exists, the practical carrying through (*Durchsetzung*) of the claim, and consequent apportionment of the burden of proof, needs to remain untouched. Such alleviating mechanisms could at best only be considered for fault dependent liability under § 823 I *BGB*.[569]

dd. For proof of a causal connection between the defective instruction, according to § 84 S. 2 Nr. 2 *AMG*, and the violated interest

This causal connection is proved if evidence can be submitted that damage occurred as a consequence of the defective information given. The psychological causation adverted to is often not certainly provable. Therefore legal scholars are content with probabilities.[570] In any case the fact that physicians do not always read the expert information, and that user instructions are seldom read by patients, cannot lead to a general denial or negation of the causal connection.[571]

In this context it was difficult for the jurisprudence to promote a reversal of the burden of proof in favour of the injured plaintiff.[572] While admitting to the fact that, while the principle of reversing the burden of proof is applied in contractual situations[573] and is also well-regarded by the legal literature in delict law liability cases[574], the Federal Supreme

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[569] Kullmann in: Kullmann/ Pfister, Kza. 3800 at 46.
[570] Deutsch, at 597 para. 903.
[571] Deutsch, *ibid.*
[572] Kullmann in: Kullmann/ Pfister, Kza. 3800 at 46.
[573] 64 *BGHZ* 46 at 51 f. = *BGH* [1975] NJW 824 at 825 - hair tonic; *BGH* [1977] VersR 918 at 921 - "plant-protective agent"; 72 *BGHZ* 92 at 106.
[574] See reference by Kullmann in: Kullmann/ Pfister, Kza. 3800 at 47.

Court nonetheless has not yet followed these approaches into the scope of delict law liability. Moreover, it has emphasised in several decisions that the alleviating mechanisms found to be applicable by the highest jurisdictions, regarding causation within the ambit of necessary but omitted user information in contracts[575], could not simply be applied in the ambit of delict law without further ado.

Concerning pharmaceutical product liability the Federal Supreme Court has - in referring to the wording of § 84 S. 2 Nr. 2 *AMG* - expressly decided that, in an action claiming damages, the injured plaintiff has to carry the burden of proof regarding this causation element and therefore needs to prove that the damage would not have occurred if the user information - or as the case may be, the labelling or expert information - had been complete and correct.[576] Within the scope of delict law liability the Federal Supreme Court, since its decision in the "children's' tea I" case, proceeds on the assumption that, when particular dangers are indicated clearly and intelligibly for the addressee, a factual presumption (*tatsächliche Vermutung*) speaks in support of the view that the damage would have been averted by a sufficient warning.[577] The scholarly jurisprudence cannot be generally applied to liability under § 84 S. 2 Nr. 2 *AMG*. It might accordingly only be open to consideration if the pharmaceutical entrepreneur has omitted to inform about a

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[575] *BGH* [1987] VersR 102 at 103- "*Verzinkungsspray*"; 99 *BGHZ* 167 at 170 ff. = *BGH* [1987] VersR 312 at 315 - "*Honda*"; 61 *BGHZ* 118 at 122 ff. - "*d-c-fix*".

[576] 106 *BGHZ* 273 at 284 - "asthma-spray", here: a sufficient and comprehensive warning against the risk of over-dosage; critic Hans Stoll, "contribution to speech from Erwin Deutsch "*Die klinische Forschung am Menschen im amerikanischen und internationalen Recht*" [1987] Karlsruher Forum 11 ff." [1987] Karlsruher Forum 33 at 35; Deutsch criticises the Court's findings and votes for application of the principles of the so called "real decision conflict" ("*echten Entscheidungskonflikts*"), developed in physician's liability cases, [1989] JZ 855 at 856.

[577] 116 *BGHZ* 60 at 73 - "children's tea I".

particularly dangerous risk,[578] or to warn unequivocally and in a manner intelligible to the patient and the physician about a specific pharmaceutical administration, where disclosure at the same time is supposed to allow the patient or physician to decide whether he wanted to take the risk.[579] Referring to the "*Estil*" case, such an alleviating mechanism for proof was found to be open to consideration, if necessary warnings to physicians were omitted and the pharmaceutical product would only be administered by a physician or under his supervision.[580] In this case it was held open to say that, as a typical consequence of an appropriate warning about dangers, it can be expected that every responsible and conscientious physician would have paid attention to the user instruction or would have declined any application of the product. Following this it was found that, with regard to simple warnings and user instructions, precautionary measures, etc., the burden of proof cannot be reversed nor may such a presumption be considered.[581]

A slightly different approach was suggested by distinguishing between user instructions and warnings. In this regard it was held that in case of a defective user instruction, which has most likely manifested itself in pharmaceutical product damage, due to the direct importance of this supporting measure of information, the reversal of the burden of proof was appropriate. In case of pure warnings on the other hand, it was found that it would be excessive to put the full burden of proof on either the patient or the pharmaceutical

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[578] Which of course has not already made the pharmaceutical product "dangerous" in the sense of the first alternative of § 84 S. 2 *AMG*.

[579] Kullmann in: Kullmann/ Pfister, Kza. 3800 at 47, of a different opinion, Rolland, in: *Festschrift für Werner Lorenz* 193 at 210.

[580] *BGH* [1972] NJW 2217 at 2221 - "*Estil*". As a distinctive decision see *OLG* Stuttgart [1990] VersR 631 at 634 - "*Impletol*", where the claim was dismissed based on the physician's testimony - as a litigation party

entrepreneur, as to whether the warning would have been followed or not. Moreover, in this context it was recommended to take over the jurisprudence on the "real decision conflict" (*"echter Entscheidungskonflikt"*) in cases of physicians' liability, if they violate their obligation to give full disclosure to their patients.[582] Accordingly, the patient has to show that in case of sufficient warning he would have found himself in a real decision conflict, whether to take the drug or not. In view of the uncertain proof situation it was found appropriate to "meet in the middle" and impose the burden of proof entirely on neither party. In this connection it was pointed out that the patient would anyway in no case be able to declare more than that. However, any case always needs consideration of the fact that liability is only imposed in the event that a connection for the imputation of responsibility (*Zurechnungszusammenhang*) has been established: if a required indication was omitted, liability does not exist for injuries, even though they occurred through application of the drug, if they were injuries which the pharmaceutical entrepreneur was not obligated to instruct about.[583]

5. Legal consequences of liability under the Pharmaceutical Products Act

According to § 84 S. 1 *AMG*, the pharmaceutical entrepreneur is obligated to compensate for the harm caused to the injured party if, as a result of administration of a drug

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- revealing to the court's conviction, that an appropriate warning would have not come to the physician's attention. Also confirmed by the Federal Supreme Court see: *BGH* [1990] VersR 1990 at 634.

[581] Kullmann in: Kullmann/ Pfister, Kza. 3800 at 47.

[582] Deutsch, at 597 para. 903; Deutsch, [1989] JZ 855 at 856.

[583] *OLG* Köln [1994] NJW RR 91 at 92 - "insect repellent spray".

distributed to the consumer, a person is killed or the body or health of a person is significantly injured, provided the other special conditions are also met.

a. The "everything-or-nothing" principle

In German damage compensation law in general, the so called "everything-or-nothing principle" applies. This means the tortfeasor is obligated to compensate the entire damage caused by the liability establishing event. If, though, the slightest doubt exists as to whether the claim establishing conditions are met, the injured party does not receive compensation at all. This principle is also valid in a case of liability under § 84 *AMG*. According to the statutory provision, the pharmaceutical entrepreneur is obligated to compensate for the harm caused to the injured party; that is, the entire damage which results from the violation of the protected interests under § 84 *AMG*. The "everything-or-nothing principle" receives only a few small qualifications by specific directions, which will be explained next.

b. Compensation of consequential damages

§ 87 *AMG* provides regulations concerning the extent of liability for damages in case of bodily injury. According to these, in case of injury to either body or health, compensation shall be given in the form of indemnification of the costs for a cure, as well as for the costs incurred through any economic detriment sustained by the injured party, as a result of his earning capacity being temporarily or permanently suspended or diminished or his needs being increased. Beside this, the pharmaceutical entrepreneur in any case also has to compensate for any damages which occurred after a significant injury to a person's

body or health through further injury of these objects of legal protection. This is because the intention behind the pharmaceutical product liability, under §§ 84 ff. *AMG*, is to allow the injured party to claim compensation for all those damages which are intimately connected with the danger presented by the pharmaceutical product.

It may well be asked: does the obligation to compensate for damages include consequential damages inflicted upon other objects of legal protection not primarily given by § 84 *AMG*, *e.g.*, to property? Such damages might occur, for example, if somebody becomes unconscious through pharmaceutical effects and thereby breaks an expensive vase which he was holding in his hands, or falls into a TV, a mirror cupboard or some valuable apparatus, or drives his car into a tree or is robbed while in a state of unconsciousness, etc.[584] According to some scholarly opinions, the injured party in those cases is referred to delict law provisions.[585] Others hold that those kinds of damages to property are not generally excluded, but only if they do not fall within the protective ambit of the Pharmaceutical Products Act. This however, does not concern consequential damages, which represent themselves as realisations of the pharmaceutical risk to which the injured party was exposed, as a result of the first injury inflicted on him and the situation created by it.[586]

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[584] Examples by Kullmann in: Kullmann/ Pfister, Kza. 3805 at 2.
[585] Sander, *AMG* § 84 para. 10 at 13.
[586] Kullmann in: Kullmann/ Pfister, Kza. 3805 at 2. With respect, in my opinion this circle around damages included seems to be drawn too generously, as it needs to be kept in mind that the Pharmaceutical Product Act primarily focuses on inadequate damages to the injured party which are socially unacceptable under considerations of financially unexpected needs. Therefore, general statements on this issue cannot be posed, as in each case of consequentially created damages to property, other than directly related to body and health injuries, such as detriment to property as a result of earning capacity being temporarily or permanently suspended or diminished, etc., one needs to carefully examine, if they fall within the protective ambit of § 84 *AMG*.

c. Extent of compensation obligation in case of death

The extent of compensation provided under the Pharmaceutical Products Act is laid down in § 86 *AMG*. In case of death, § 86 I *AMG* allows compensation by indemnification for the costs of an attempted cure, as well as for costs incurred by the detriment to property sustained by the deceased party as a result of his earning capacity being temporarily or permanently suspended or diminished or his needs being increased. The party liable for damages furthermore needs to reimburse the funeral costs to the party bound to defray these expenses. According to § 86 II *AMG*, the party liable for damages has to indemnify a third party, guaranteeing maintenance to the extent to which the deceased party would have been liable for the length of life-span he would probably have had, provided that at the time of injury the deceased party maintained a relationship with the third party by virtue of which he was or could come under the legal obligation to support this third party, and the third party was deprived of the right to maintenance as a result of the death. The liability for damages is also enforced in favour of a third party who, at time of injury, was conceived though not yet born.

d. Maximum liability amounts

The Pharmaceutical Products Act limits the defendant's liability to maximum amounts set out in § 88 *AMG*. In cases of death or injury, a person § 88 S. 1 Nr. 1 *AMG* provides for a capital amount of up to one million Deutschmarks or an annuity of up to sixty thousand Deutschmarks. In case of death or injury of several persons by the same drug, notwithstanding the conditions of Nr. 1, § 88 S. 1 Nr. 2 *AMG* allows for a capital amount

of up to two hundred million Deutschmarks or an annuity of up to twelve million Deutschmarks. § 88 S. 2 *AMG* limits the liability amount, if in the case of § 88 S. 1 *AMG*, the indemnification to be paid to the several injured parties should exceed the maximum amounts specified therein. Then the individual compensation shall be decreased to the same extent that the total amount relates to the maximum amount.

e. Influence of contributory negligence on the extent of the compensation obligation

aa. Contributory negligence during the stage of damage establishment

If in the stage of establishment of damage, the negligence of the injured party[587] has contributed to causing that damage, § 85 *AMG* declares § 254 *BGB* applicable. Under the provision of § 245 I *BGB*, the obligation to compensate the injured party, and the extent of the compensation to be made, depends upon the circumstances, especially upon how far the injury has been caused predominantly by the one or the other party. Even though it is conditional for the application of § 254 *BGB*, that during the establishment of damage the injured party's negligence has made some contribution, it requires an evaluation which primarily has to be focused on the causation contributed by each party, respectively. Additionally, then, such contributory negligence needs to be evaluated.[588]

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[587] This means that the injured party did not take the necessary measures of care required and expected by an orderly and reasonable person to avoid his own or prevent himself from damage to himself; Kullmann in: Kullmann/ Pfister, Kza. 3805 at 6; Sander, *AMG* § 85 para. 1 at 1.

[588] Kullmann in: Kullmann/ Pfister, Kza. 3805 at 6.

First any contributory negligence on the part of the injured person in this context can be taken into account, if it is due to conduct **before** or **during** administration of the pharmaceutical product. *E.g.*, if the injured party has, by misuse in the concrete situation, enlarged the damage he has sustained,[589] which would have also occurred by the drug's application under appropriate, ordinary and intended use, this would have established the pharmaceutical entrepreneur's liability. This might, for example, be achieved by over or under dosage, or by failure to comply with other instructions giving counter-measures. Contributory negligence is also open to consideration, if the party injured by the drug has exacerbated or prolonged the damage by excessive stress to his body.[590]

If damage is solely due to negligent use, contrary to the intended use, or due to non-observance of labelling or user instructions, the extent of the compensation obligation might not only be curtailed by the contributory negligence of the injured party; but it might be wholly eliminated, relieving the pharmaceutical entrepreneur from any liability at all.[591]

Secondly, contributory negligence on the part of the injured person can also ensue from conduct **after** drug administration. These are basically cases where the injured party, due to non-observance of instruction after the drug administration, increases the damage incurred.[592]

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[589] Kloesel/ Cyran, *AMG* § 85 para. 2 at 105; Sander, *AMG* § 85 para.3 at 2.
[590] Kloesel/ Cyran, *AMG* § 85 para. 3 at 105 with further examples, also Sander, *AMG* § 85 para. 2 at 1 f.
[591] Kullmann in: Kullmann/ Pfister, Kza. 3805 at 7.
[592] Sander, *AMG*, Erl. § 85 para. 2 at 2, Kloesel/ Cyran, *AMG*, § 85, para. 1; Kullmann in: Kullmann/ Pfister, Kza. 3805 at 7.

bb. Contributory negligence, or failure to mitigate in the stage of damage development by not averting or not reducing the damage

Besides contributory negligence, in the context of the emergence of damage from the violation of protected interests, it is also possible to imagine contributory negligence in the context of so-called damage completion. This might exist in circumstances where the injured party fails to avert or reduce the impending damage caused by a violation of protected interests.[593] *E.g.*, by failing to consult a physician's help, or to undergo treatment or an operation, by the non-administration of necessary drugs, by not following a special diet or even by not using one's remaining capacity to work, in cases of reduction or partial incapacity to earn a living.[594]

Gross malperformances or mistreatments by the physician cannot be held against the injured party in this context. They might only be considered under the question of adequate causal connection, between the violation of the patient's or consumer's protected interests and the damage incurred.[595]

6. Limitation of actions

The claim specified in § 84 *AMG* is limited in point of time, just like claims under delict law (§ 852 *BGB*). According to § 90 *AMG*, the specified period is three years from the

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[593] Sander, *AMG* § 85 para. 3 at 2.
[594] Kullmann in: Kullmann/ Pfister, Kza. 3805 at 8.

date on which the party entitled to damages actually becomes aware of the injury, of the circumstances leading to his right to file a claim and of the identity of the party liable for damages. In any case, the claim ceases to be valid after a period of thirty years following the incurring of the damages.

In case of bodily injury through pharmaceutical products, the significant or critical knowledge of damage only exists when the injured party could point to damage suggestive of liability, namely a significant injury to his body or health, which is traceable back to the drug administration.[596]

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[595] Kullmann in: Kullmann/ Pfister, Kza. 3805 at 9.
[596] Sander, *AMG* § 90 para. 2b at 2.

Part 2: Canadian Law:

A. Product liability and the law of negligence

In contrast to German product liability law, Canadian law does not provide for fault independent liability, such as the German Product Liability Act or the Pharmaceutical Product Act regarding pharmaceutical products. It is only based on fault dependent liability, namely the law of negligence. This means liability is imposed on manufacturers for any damage caused to a consumer by product defects that are due to their breach of the duty of care.

I. The manufacturer's duty of care; product defects or liability categories

One basic focus in the concept of product liability is the defective product, which means that the product in question falls short of what it ought to have been in view of a reasonable standard at the time of distribution, and therefore is in a condition unreasonably dangerous to the consumer or to his property.[597]

In accordance with this, Canadian product liability law distinguishes between products that are defectively produced - also referred to as products with design[598] or manufacturing defects - and those that contain inherent risks. In the latter the product may be dangerous but may not be considered defective, if accompanied by adequate warnings or instructions for use.

1. Product defects

A product is considered defective if, due either to a failure in manufacture or production it does not comply with its intended design[599] or if indeed it was the design itself that was deficient[600] and which then caused the product to be defective as well. These kinds of product defect correspond with the categories of defect in manufacture and design established in the German product liability law.

No differences apply in either legal system regarding the duty of quality control and product monitoring. After a product is manufactured, but before it is put out into the stream of commerce, it might need to be carefully examined in view of possible quality defects. During this last stage of product preparation or processing a failure or deficiency might occur, in observing and controlling the product before it is distributed in order to prevent or avoid any defects, which might make particular goods less safe than the product in general. Typical examples are contaminated blood or semen products; even though they are not actually manufactured, they have been especially processed and prepared and should therefore be properly checked before being put into public circulation.[601]

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[597] S. M. Waddams, *Products Liability*, 3rd ed. (Scarborough: Carswell, 1993) at 38.
[598] *Ibid.*
[599] Waddams, *ibid.*
[600] Waddams, 39 f.
[601] See *Ter Neutzen v. Korn*, [1995] 3 S.C.R. 674, 127 D.C.R. (4th) 577; *Walker and Osborne Estate v. Red Cross*, (1998) 39 C.C.L.T. (2nd) 1 (Ont. Gen. Div.) [sub. nom. *Walker Estate v. York-Finch General Hospital*]; *Pittman v. Bain*, (1994) 19 C.C.L.T. (2nd) 1, 112 D.L.R. (4th) 257 (Ont. Gen. Div.).

The same might apply to products which have been held in stock after being produced, if they have become obsolete in the meantime due to a newly discovered standard.[602]

2. Inherent risks

Some products are not considered defective in themselves but, due to their very nature, carry certain dangers which make the risk of injury inherent and unavoidable. Many products are dangerous and accepted as such in order to be used for their intended purpose; *e.g.*, guns, kitchen knives, certain drugs. However, their use can be made reasonably safe by giving adequate warnings about the inherent risk and danger, or sufficient user instructions as to how to avoid or prevent the occurrence of injuries and damages. In Anglo-Canadian law this is commonly referred to as the duty to warn, even though, similarly to the German law, distinctions are made between the duty to give necessary user instructions and the duty to issue warnings.[603]

a. Instruction defects

Here the product in itself is - even though dangerous - not considered defective. The danger lies in its nature and is unavoidable. But damages can be avoided or the risk of damages can be reduced, if the product is appropriate and carefully used. The defect in this case is a lack of instructions corresponding to these kinds of danger, instructions

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[602] Waddams, at 43 f.
[603] Waddams, at 40 footnote 148 referring to *Murphy v. St. Catherines Gen. Hospital* [1964] 1 O.R. 239 at 256 quoting *Beckett v. Newalls Insulation Co.* [1953] 1 All E.R. 250.

which the manufacturer owes to assure that the product is only used in a safe way. Therefore, sometimes information or instructions need to be given to the consumer for the ordinary intended and contemplated use of a product. *E.g.*, in cases of pharmaceutical products, instructions are supposed to refer to the side-effects of a drug and if applicable to effects of interaction with other pharmaceutical products.

b. Warnings

Other situations require that the consumer be put in a position where the potentially harmful effects of a product are fully disclosed to him. Defects in warning exist, if the consumer is not sufficiently and explicitly warned against dangers arising from the product's intended and contemplated use[604]. Occasionally that is true also, if he was not warned about other dangerous effects related to other forms of reasonably foreseeable use[605], excluding intentional abuse[606].[607] This kind of obligation is well known in pharmaceutical product liability law as including the duty to warn on the package insert about the interaction of different products. However, no duty to warn is imposed when

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[604] *Lambert v. Lastoplex Chemicals Co. Ltd.* [1972] S.C.R. 569, 25 D.L.R. (3rd) 121 at 121/125; duty to specify attendant dangers and detailed disclosure of dangers; the explicitness of the warning will vary with the danger likely to be encountered in the ordinary use of the product. A general warning *e.g.*, "product is inflammable" will not be enough, where the likelihood of fire may be increased according to the surroundings in which it may reasonably be expected that the product will be used.
Buchan v. Ortho Pharmaceutical (Canada) Ltd., (1986) 35 C.C.L.T. 1, 54 O.R. (2nd) 92, 25 D.L.R. (4th) 658 (Ont. C.A.): the decision gives details about the contents of the warning.

[605] Waddams, at 46 f.

[606] Waddams, at 53 f.

[607] *Lem v. Barotto Sport Ltd.* (1976) 1 C.C.L.T. 180 at 180 f., 69 D.L.R. (3rd) 276 (Alta. C.A.): additional duty, when misuse of the product is reasonably foreseeable, to warn of such misuse; explicit warning concerning those dangers which might arise out of the reasonably foreseeable fault on the part of the user in its contemplated use this case is an example for extreme misuse (intentional abuse?).

obvious dangers are necessarily incidental to the product's use, such as drinking alcohol.[608]

3. Post-marketing duties, reactive duty to warn

Corresponding to the German product liability law, the Canadian law imposes duties on the manufacturer after product distribution. The existence of such post-marketing duties is based on the idea that the manufacturer's duties do not end after the product is on the market. One of his most important duties is the duty of monitoring the product, which means an obligation of continuously observing the product's effects and quality, to discover hitherto unknown product deficiencies in regard to new standards and changes in science and technological knowledge. Some products reveal their inherent dangers or potential harmful effects after they have been distributed and used. Sometimes subsequent developments in the state of the art now show the product to be defective. The subsequent discovery of such defects leads to corresponding reactive duties of the manufacturer, such as to warn, when he is able to address the consumers. Where the duty to warn the consumer or the public about certain dangers in connection with the product would be considered not to be an adequate or reasonable response, to prevent the

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Smithson et al. v. Saskem Chemicals LTD. et al. (1985) 34 C.C.L.T. 195, [1986] 1 W.W.R. 145, 43 Sask. R. 1 (Q.B.): no warning about mixture of two violently incompatible drain-cleaning compounds.

[608] *Lem v. Barotto Sport Ltd.* at 181: when the dangers of use or misuse are so well known, a warning in respect of them may not be necessary.
Deshane v. Deere & Co. (1993) 17 C.C.L.T. (2nd) 130 (4th) (Ont. C.A.) at 131: machine was used in a certain way in a function it was not designed for. This extremely dangerous use of the machine was patently obvious to anyone who looked at it.

expected damage likely to be caused by the product, the manufacturer's duty can become a duty to recall or withdraw his product from the market.[609]

Distinct from the situation that arises out of subsequent developments in the state of the art is where a subsequent improvement concerning the product is discovered, such as a safety device that could be installed on existing products.[610] New scientific developments bring up a new safety standard affecting all products as of that time, so that they necessarily have to meet the requirements of the new standard; *e.g.*, prohibition of thalidomide products as sleeping drugs. Subsequent improvements might enhance safety at the same time, but they do not have the same impact on existing older products, that will be considered as defective. For instance, the installation of seat belts in cars has become a general practice to meet the requirements in safety standards of the present time, but the manufacturers were not held responsible to install seat belts in all the cars they had ever sold before? This raises the question of whether subsequent improvements impose on the manufacturer a positive duty to act.[611] That will probably depend on the quality of the danger that could possibly be reduced in relation to the effort that can reasonably be expected from the manufacturer. Here we obviously have to make distinctions in terms of improvements between additional safety devices and those that are serious attempts to avoid inherent dangers of the product.

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[609] *Rivtow Marine v. Washington Iron Works* [1974] (1972) S.C.R. 1189, 40 DLR (3d) 530 (S.C.C.).
[610] Waddams, at 45.
[611] *Ibid.*

B. The pharmaceutical manufacturer's duty to warn[612]

I. The duty to warn

1. General principles

It is well established in Canadian law that a manufacturer of a product has a duty in tort to warn consumers of dangers inherent in the use of its product, when it has knowledge or ought to have knowledge.[613] This principle originated in the classic statement of Lord Atkin in *Donoghue v. Stevenson*, followed by the Supreme Court of Canada in *Lambert v. Lastoplex Chemicals Co.*:

> Manufacturers owe a duty to consumers of their products to see that there are no defects in manufacture which are likely to give rise to injury in the ordinary course of use. Their duty does not, however, end if the product, although suitable for the purpose for which it is manufactured and marketed, is at the same time dangerous to use; and if they are aware of its dangerous character they cannot, without more, pass the risk of injury to the consumer.[614]

The duty to warn is a continuing one, requiring manufacturers to warn not only of dangers known at the time of sale, but also of dangers discovered after the product has been sold

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[612] Observation: The main focus of this thesis is not on the investigation of the law of defective products. Rather it is about products that are inherently or unavoidably dangerous. Utility is the argument for the explanation of why they are nevertheless on the market, see *Buchan* at 15. My thesis is based on the assumption that the pharmaceutical products under consideration are safe enough to be put on the market, because they have the stamp of governmental approval, without which they cannot be sold. But the procedure for getting this governmental approval is not the topic of this thesis either. Here I proceed on the assumption that any drug, prosthesis, or other medical product in issue in any case is one that has at least been approved by the appropriate regulatory authority. Hypothesis: I am dealing with approved drugs and other medical products that have unavoidable dangers, but which on grounds of utility are approved for use in medical treatment. Nor will the Food and Drug Act be discussed.

[613] *Hollis v. Dow Corning Corp.* [1995] 27 C.C.L.T. (2d) 1 at 19: hereafter cited as *Hollis*; *Buchan v. Ortho Pharmaceutical (Canada) Ltd.* [1985] 35 C.C.L.T. 1 at 12: hereafter cited as *Buchan*; Waddams, at 45.

[614] 25 D.L.R. (3d) 121 at 124f.

and delivered.[615] This obligation arises out of the duty to minimize potential harmful effects by issuing warnings of dangers subsequently discovered. This duty applies to dangers that ought to be known as well as to those actually known.[616]

This was stated in *Rivtow Marine Ltd. v. Washington Iron Works Ltd.*, where the Supreme Court of Canada imposed liability on a manufacturer of defective goods for failing to issue a warning to former purchasers, as soon as the notice of the defect came to the manufacturer's attention.

> ...the knowledge of the danger involved in the continued use of these cranes for the purpose for which they were designed carried with it a duty to warn those to whom the cranes had been supplied, and this duty arose at the moment when the respondents or either of them became seized with the knowledge.[617]

This case determined that there might be a positive duty to act, particularly if the danger is not obvious to the consumer and if the user of the product could conveniently be contacted. The case imposed liability for an omission at a point in time later than the actual distribution of the product.[618]

2. Pharmaceutical and medical products

The duty to warn about inherent dangers of a product refers in the same manner to manufacturers of pharmaceutical and medical products. The general rule at common law is that the manufacturer of such drugs has a duty to provide consumers with adequate warning of the potentially harmful side-effects that the manufacturer knows, or has reason

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[615] *Hollis* at 19.
[616] Waddams, at 44 f. with further references.
[617] [1974] S.C.R. 1189 at 1200.

to know, may be produced by the drug.[619] This law was affirmed in the judgment in *Buchan v. Ortho Pharmaceutical*:

> In the present state of human knowledge, many drugs are clearly incapable of being made totally safe for their intended or ordinary use, even though they have been properly manufactured and are not impure or defective. But notwithstanding a medically recognizable risk, their marketing may be justified by their utility. Apart from any regulatory scheme under the Food and Drugs Act, the general rule at common law is that the manufacturer of such drugs, like the manufacturer of other products, has a duty to provide consumers with adequate warning of the potentially harmful side-effects that the manufacturer knows or has reason to know may be produced by the drug.[620]

This shows, that the pharmaceutical manufacturer's duty to warn exists as such in both product liability systems, the Canadian and the German.

II. Contents and scope of the warning

1. Adequacy of the warning

The question here is: When is the content of the warning adequate[621]?

The answer: When it provides clear, complete and current information concerning the dangers inherent in the ordinary use of the product.[622]

All warnings must be reasonably communicated and must clearly and fully describe any inherent dangers that arise from the ordinary use of the product;[623] in other words, the warning requires a precise degree of specificity.[624]

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[618] Waddams, at 45.
[619] *Davidson v. Connaught Laboratories* (1980) 14 C.C.L.T. 251 (Ont. H.C.) at 273: hereafter cited as: *Davidson v. Connaught Laboratories*.
[620] *Buchan*, at 15.

This is basically the same as demanded by German product liability law.

In *Buchan v. Ortho Pharmaceutical (Canada) Ltd.*, Robins J.A. citing *Donoghue v. Stevenson*, *Lambert v. Lastoplex*, and *Rivtow Marine Ltd. v. Washington Iron Works*, described as follows the nature of the warning required:

> Once a duty to warn is recognized, it is manifest that the warning must be adequate. It should be communicated clearly and understandably in a manner calculated to inform the user of the nature of the risk and the extent of the danger; it should be in terms commensurate with the gravity of the potential hazard; and it should not be neutralized or negated by collateral efforts on the part of the manufacturer. The nature and extent of any given warning will depend on what is reasonable having regard to all the facts and circumstances relevant to the product in question.[625]

The general principle to be applied in determining the degree of explicitness required in a warning was enunciated by the Supreme Court of Canada in *Lambert v. Lastoplex Chemicals Co.*,[626] as follows:

> The applicable principle of law according to which the positions of the parties in this case should be assessed may be stated as follows. Where manufactured products are put on the market for ultimate purchase and use by the general public and carry danger (in this case, by reason of high inflammability), although put to use for which they are intended, the manufacturer, knowing of their hazardous nature, has a duty to specify the attendant dangers, which it must be taken to appreciate in a detail not known to the ordinary consumer or user. A general warning, as for example, that the product is inflammable, will not suffice where the likelihood of fire may be increased according to the surroundings in which it may reasonably be expected that the product will be used. The required explicitness of the warning will, of course, vary with the danger likely to be encountered in the ordinary use of the product.[627]

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[621] Term also used in *Buchan* at 26 ff. and by Patricia Peppin, *"Drug/Vaccine Risks: Patient Decision Making and Harm Reduction in the Pharmaceutical Company Duty to warn Action"* (1991) 70 Canadian Bar Review (Can. Bar Rev.) 473 at 486, with further detailed information: hereafter cited as Peppin.
[622] *Hollis* at 21.
[623] *Hollis* at 19.
[624] *Davidson* at 273.
[625] *Buchan* at 12 f.
[626] 25 D.L.R. (3d) 121 at 125.

The previous quotation shows that the nature and scope of the warning varies with the level of danger involved in the ordinary use of the product. Where significant dangers exist in that ordinary use, a general warning concerning such dangers does not meet the required adequacy of the duty; the warning must be sufficiently detailed to give the consumer a full indication of each of the specific dangers arising from use of the product.[628]

In this regard it was found that directions for use will not always protect the manufacturer from liability for serious consequences, unless the risk is obvious.[629] Corresponding to the German law, a warning must indicate not only the likelihood of the danger occurring, but also the seriousness of the likely consequences[630] and an indication as to how the harm is likely to occur[631].

The question of adequacy of the warning leads to the following consideration. The duty to warn serves to correct the knowledge imbalance between manufacturers and consumers by disclosing any dangers to the consumer needed for appropriate and safe usage of the product.[632] One must be put into a position where he is fully informed about the inherent risks faced or exposed to by using the product, in order to be able to protect one's self from any damage that might occur to him. He also needs to receive all the information

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[627] *Buchan* at 13.
[628] *Hollis* at 20.
[629] Waddams, at 51 footnote 185, referring to *Austin v. 3M Can. Ltd. (1974)*, 7 O.R. (2d) 200, 53 D.L.R. (3d) 656 (Co. Ct.).
[630] Waddams, at 51; in footnote 186, referring to *O'Fallon v. Inecto Rapid (Can.) Ltd.*, [1939] 1 W.W.R. 264, 53 B.C.R. 266 (S.C.).
[631] Waddams, at 51 footnote 187, referring to *Ruegger v. Shell Oil Co.*, [1964] 1 O.R. 88, 41 D.L.R. (2d) 183 (C.A.).
[632] *Hollis* at 19.

necessary to make informed decisions, concerning whether to use the product at all after carefully balancing the advantages and dangers entailed by use of the product.[633]

This was made clear in *Hollis*:

> The rationale for the manufacturer's duty to warn can be traced to the "neighbour principle", which lies at the heart of the law of negligence, and was set down in its classic form by Lord Atkin in *Donoghue and Stevenson*, [1932] A.C. 562 (H.L.). When manufacturers place products into the flow of commerce, they create a relationship of reliance with consumers, who have far less knowledge than the manufacturers concerning the dangers inherent in the use of the products, and are therefore put at risk if the product is not safe. The duty to warn serves to correct the knowledge imbalance between manufacturers and consumers by alerting consumers to any dangers and allowing them to make informed decisions concerning the safe use of the product.[634]

2. Standard for pharmaceutical and medical products

There is no major difference regarding the standard of care, which is necessarily high in the case of medical products in both legal systems. The German jurisprudence is to the same effect. Corresponding to the German courts, the courts in Canada have long recognised that manufacturers of products that are ingested, consumed or otherwise placed in the body, and thereby have a great capacity to cause injury to consumers, are subject to a correspondingly high standard of care under the law of negligence.[635]

> In the case of medical products such as the breast implants at issue in this appeal, the standard of care to be met by manufacturers in ensuring that consumers are properly warned is necessarily high. Medical products are often designed for bodily ingestion or implantation, and the risks created by their improper use are obviously substantial.... Given the intimate relationship between medical products and the consumer's body, and the resulting risk created to the consumer, there will almost always be a heavy onus on manufacturers of medical products to provide clear,

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[633] This is closely akin to the full disclosure standard that is required in doctor-patient relationships, known as the idea of "informed consent".
[634] *Hollis* at 19.
[635] *Hollis* at 20 with further footnotes.

> complete and current information concerning the dangers inherent in the ordinary use of their product.[636]

Concerning the adequacy of the warning in the case of medical products, La Forest J. leads in his statement in *Hollis* to an analogy to the "informed consent" doctrine,[637] used in the doctor - patient relationship.

> I pause at this point to observe that there is an important analogy to be drawn in this context between the manufacturer's duty to warn and the doctrine of "informed consent" developed by this court in recent years with respect to the doctor-patient relationship. In *Hopp v. Lepp*. [1980] 2 S.C.R. 192, at pp. 195-196, 210, and *Reibl v. Hughes*, [1980] 2 S.C.R. 880, at pp. 884-885, this court decided that physicians have a duty, without being questioned, to disclose to a patient the medical risk of a proposed procedure, its gravity, and any special or unusual risks, including risks with low probability of occurrence, attendant upon the performance of the procedure; further references omitted. The principle underlying "informed consent", as Laskin C.J.C. explained in *Hopp*, supra, at p. 196, is the "right of a patient to decide what, if anything, should be done with his body": see also *Schloendorff v. Society of New York Hospital*, 105 N.E. 92 (N.Y. Ct. App., 1914), per Cardozo J. The doctrine of "informed consent" dictates that every individual has a right to know what risks are involved in undergoing or foregoing medical treatment and a concomitant right to make meaningful decisions based on a full understanding of those risks. [Further references omitted].
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> In my view, the principles underlying the doctrine of "informed consent" are equally, if not more, applicable to the relationship between manufacturers of medical products and consumers than to the doctor-patient relationship. The doctrine of "informed consent" was developed as a judicial attempt to redress the inequality of information that characterizes a doctor-patient relationship. An even greater relationship of inequality pertains both between the manufacturer of medical products and the consumer and, to a lesser degree, between the manufacturer and the doctor. In contrast to the doctor-patient relationship, where the patient can question the doctor with respect to the risks and benefits of particular procedures and where doctors can tailor their warnings to the needs and abilities of the individual patients, the manufacturer-consumer relationship is characterized primarily by lack of direct communication or dialogue. This lack of dialogue between manufacturer and consumer creates, as Patricia Peppin notes in "Drug/Vaccine Risks: Patient Decision Making and Harm Reduction in the Pharmaceutical Company Duty to warn Action", (1991) 70 Can. Bar Rev. 473, at p. 474, a relationship of complete dependency between manufacturer and patient....[638]

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[636] *Hollis* at 20 f.
[637] *Reibl v. Hughes* [1980] 2 S.C.R. 880 established at 884-885 the full disclosure standard, to correct the knowledge and information imbalance between physician and patient: hereafter cited as *Reibl*.
[638] *Hollis* at 21 f.

A similar observation was made by Robins J.A. in *Buchan v. Ortho Pharmaceutical (Canada) Ltd.*, with the following additional arguments:

> As between drug manufacturer and consumer, the manufacturer is a distant commercial entity that, like manufacturers of other products, promotes its products directly or indirectly to gain consumer sales, sometimes, as in this case, accentuating value while under-emphasizing risks. Manufacturers hold an enormous informational advantage over consumers and, indeed over most physicians. The information they provide often establishes the boundaries within which a physician determines the risks of a possible harm and the benefits to be gained by a patient's use of a drug.[639]

This leads La Forest, J. in his judgment to *Hollis*[640] to the following conclusion:

> In light of the enormous informational advantage enjoyed by medical manufacturers over consumers, it is reasonable and just to require manufacturers, under the law of tort, to make clear, complete and current informational disclosure to consumers concerning the risks inherent in the ordinary use of their products. A high standard for disclosure protects public health by promoting the right to bodily integrity, increasing consumer choice and facilitating a more meaningful doctor-patient relationship.

At the same time, it cannot be said that requiring such a high standard of disclosure from drug manufacturers would impose an onerous or undue burden on them.[641] As Robin J. A. explained in *Buchan*:

> ... drug manufacturers are in a position to escape all liability by the simple expedient proving a clear and forthright warning of the dangers inherent in the use of their products of which they know or ought to know.[642]

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[639] *Buchan* at 34.
[640] *Hollis* at 23
[641] *Hollis* at 23.
[642] *Buchan* at 35.

This standard for pharmaceutical products has been extended to a degree where the manufacturer is even obliged to inform about potential risks that are not exactly developed and remain uncertain, but might appear in usage of the product.

> Whether a particular warning is adequate will depend on what is reasonable in the circumstances. ...While a low probability of injury or a small class of endangered users are factors to be taken into account in determining what is reasonable, these factors must be balanced against such considerations as the nature of the drug, the necessity for taking it, and the magnitude of the increased danger to the individual consumer. Similarly, where medical evidence exists which tends to show a serious danger inherent in the use of a drug, the manufacturer is not entitled to ignore or discount that information in its warning solely because it finds it to be unconvincing; the manufacturer is obliged to be forthright and tell the whole story. The extent of the warning and the steps to be taken to bring the warning home to the physician should be commensurate with the potential danger - the graver the danger, the higher the duty.[643]

However, the required standard of information-disclosure, its extent and preciseness, might vary depending on the situations and might be sometimes less strict when warnings are not meant to be directly communicated to consumers but to experts, who are presumed to know certain things which may not be expected of the general public. Sometimes, on the other hand, it might be just a different - as opposed to a lower - standard required towards experts. This will be determined by the circumstances of each case, *i.e.*, the need of information demanded for the sake of the public's security.

> The Lambert case deals more with the warning to a consumer than it does to an expert. There is in some situations a less strict standard in communicating with experts, who are presumed to know certain things, whereas the public generally may not be expected to know of those things. On the other hand, there may be some things that one would be required to communicate to experts, that one would not tell the general public about. As in everything in our law, and particularly in the law of negligence, it always depends upon the circumstances. The question to be asked is, "What is a fair and reasonable warning in all the circumstances of the case?".[644]

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[643] *Buchan* at 26 f.

Finally it should be mentioned in this context that independently received knowledge, by either the consumer or the physician, does not affect the manufacturer's duty to warn as such, which is generally non-delegatable and is continuous in spite of the availability of information elsewhere.[645]

III. The design of the warning

Just as in the German law, there is no hard and fast rule as to how a warning needs to be designed regarding size, colour, print and use of particular words. The only test is whether the warning used is in all the circumstances sufficient to bring home to a reasonable user the true extent of the risk involved and of the precautions required.[646] The requirements might vary from case to case and will depend on the risks and dangers involved. Most likely more will be demanded where dangers for human bodies and health exist. Considering the fact that meaning and impact of words can change quickly, the onus is on the manufacturer to ensure that the warning represents the true danger according to current usage.[647]

Like the German law, the Canadian law demands that a warning given in the literature accompanying the product be repeated also on the product's package or container, where the occasion calls for it.[648]

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[644] *Davidson*, (1980) 14 C.C.L.T. 251 at 273 f.
[645] Peppin, at 512.
[646] Waddams, at 50 f.
[647] Waddams, at 51.

IV. Addressee of the warning and the "learned intermediary"[649] rule

The question now is: To whom should the manufacturer address the warning?

The duty to warn is owed to the person most likely to get injured, which is usually the user of the product. Therefore, the warning generally needs to be addressed directly to the ultimate consumer. This duty will, in the case of pharmaceutical products, ideally be fulfilled by providing the medication or drug container with a label or package insert that adequately reveals the known and potential dangers and side effects involved in using the product.

This general observation, however, has exceptions when a third person, who is in certain cases called a "learned intermediary"[650], is interposed between the manufacturer and the consumer in the usage of the product. In these cases, the duty of manufacturers to warn consumers is discharged if the manufacturer provides the learned intermediary, rather than the consumer, with adequate warning of the potential danger.[651]The result of this is that under certain circumstances a direct warning from the manufacturer to the ultimate consumer may not be required.

Where, for example, the product is a highly technical one, intended or expected to be used only under the supervision of experts, a warning to those experts will suffice.[652]

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[648] *Ibid.*, footnote 189 referring to *O'Fallon v. Inecto Rapid (Can.) Ltd.*, [1939] 1 W.W.R. 264, 53 B.C.R. 266 (S.C.).

[649] N. Rafferty & P.A. Rowbotham, *"Liability or Manufacturer of Silicone Breast Implants to a Patient: Hollis v. Dow Corning Corp."* (1997) 8 Supreme Court Law Review (2^{nd} series) 159 at 161: herafter cited as (S.C.L.R.), for a good overview and definition to the "learned intermediary" rule: hereafter cited as Rafferty & Rowbotham.

[650] *Buchan* at 15; further examples Waddams, at 52 footnote 194.

[651] *Buchan* at 15, Rafferty & Rowbotham, at 162.

[652] *Buchan* at 12.

The learned intermediary concept first appeared in American courts in connection with cases about the liability of manufacturers of prescription drugs, and it was those courts which termed it the "learned intermediary" rule.[653] In the absence of similar approaches in Canadian or English case law, this considerable body of American cases was reflected upon by Canadian courts and first referred to in an *obiter* passage by Linden J. in *Davidson v. Connaught Laboratories*[654] and later applied by the Ontario Court of Appeal in *Buchan v. Ortho Pharmaceutical*[655] and by the Supreme Court of Canada in *Hollis v. Birch*[656]. While the rule was originally intended to reflect, through an equitable distribution of tort duties, the tripartite informational relationships among prescription drug manufacturers, physicians and patients, the Supreme Court of Canada determined the rationale for the rule to be clearly applicable in other medical and indeed non-medical contexts.[657] According to the Supreme Court, the rule is not a new idea but just another application of the long established common law principle more familiarly known as the

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[653] The history of the "learned intermediary" rule is described in the Canadian cases of *Buchan* at 14-16 and *Hollis* at 23 f., with references to the multitude of relevant American cases. In *Hollis* reference is made as follows:

> The "learned intermediary" rule was first elaborated in *Sterling Drug Inc. v. Cornish*, 370 F. 2d 82 (8th Cir., 1966), a suit brought by a patient blinded after taking the drug chloroquine phosphate. The rationale for the rule was outlined by Wisdom J. in *Reyes v. Wyeth Laboratories*, 498 F. 2d 1264 (5th Cir., 1974), at p. 1276, certiorari denied 419 U.S. 1096 (1974), a suit against a manufacturer of oral polio vaccine. The rule was later reaffirmed and developed in a series of American cases during the 1970s and 1980s involving the liability of manufacturers of prescription drugs; see, for example, *Schenebeck v. Sterling Drug Inc.*, 423 F. 2d 919 (8th Cir., 1970); *Hoffman v. Sterling Drug Inc.* 485 F. 2d 132 (3rd Cir., 1973); *Dunkin v. Syntex Laboratories Inc.*, 443 F. Supp. 121 (W.D. Tenn., 1977); *Lindsay v. Ortho Pharmaceutical Corp.*, 637 F. 2d 87 (2nd Cir., 1980); *Timm v. Upjohn Co.*, 624 F. 2d 536 (5th Cir., 1980), certiorari denied 449 U.S. 1112 (1981); *Stanback v. Parke, Davis & Co.* 657 F. 2d 642 (4th Cir., 1981); *Walker v. Merck & Co.*, 648 F. Supp. 931 (M.D. Ga., 1986), affirmed 831 F. 2d 1069 (11th Cir., 1987); *Plummer v. Lederle Laboratories*, Division of American Cyanamid Co., 819 F. 2d 349 (2nd Cir., 1987).

[654] *Davidson v. Connaught Laboratories* at 277.

[655] *Buchan* at 14-16.

[656] *Hollis* at 25 f.

[657] *Hollis* at 24.

intermediate examination concept. This is in turn best viewed as a particular application of the still broader idea of the intervening cause doctrine, often expressed as *novus actus interveniens.*

Therefore, a warning to the ultimate user may not be necessary or may not even be expected, where intermediate examination is anticipated or the intervention of a learned intermediary is assumed.[658] In cases such as that, the nature of the product is such that the consumer will not realistically receive a direct warning from the manufacturer before he comes into contact with the product.[659] Some manufactured products are expected to be applied to others by experts and are therefore not usually sold directly through stores, which sell them "over the counter" to the ultimate consumer. These are instead supplied to professionals, for example, hairdressers[660]. In *Holmes v. Ashford*, the English Court of Appeal pointed out:

> In the present case... it must have been in the contemplation of the manufacturers supplying these goods to hairdressers that hairdressers may be expected to interpose their judgment and reason whether they are going to use a hair dye or not. In my view, if they give a warning which, if read by a hairdresser, is sufficient to intimate to him the potential dangers of the substance with which he is going to deal, that is all that can be expected of them. I think it would be unreasonable and impossible to expect that they should give warning in such form that it must come to the knowledge of the particular customer who is going to be treated. Counsel for the plaintiff says they must take reasonable steps to see that it will come to the notice of any customer. I cannot contemplate any steps which could be calculated to bring a matter of this kind to the knowledge of any person who is treated with the preparation. The most that can be expected of the manufacturers of goods of this kind is to see that the hairdresser is sufficiently warned.[661]

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[658] *Buchan* at 12.
[659] *Hollis* at 24.
[660] Hair dye for professional use by hairdressers was concerned in *Holmes v. Ashford*, [1950] 2 All E.R. 76 (C.A.); Waddams, at 52 footnote 191 with further examples.
[661] [1950] 2 All E.R. 76 (C.A.) at 80.

Similar patterns can be found in cases where physicians[662] or hospitals[663] were involved. In *Hollis v. Birch*, breast implants were directly obtained by the surgeon, Dr. Birch, to be used for their intended purpose and neither the product nor its packaging were to be placed into the hands of the ultimate consumer. Therefore, the surgeon as the expert was considered to be in the best position to read the instructions and any warnings contained in the product packaging. He could therefore be reasonably expected by the manufacturer to pass this information on to the patient.

> ... it is my view that the "learned intermediary" rule is applicable in this context, and that Dow was entitled to warn Dr. Birch concerning the risk of rupture without warning Ms. Hollis directly. A breast implant is distinct from most manufactured goods in that neither the implant nor its packaging are placed directly into the hands of the ultimate consumer. It is the surgeon, not the consumer, who obtains the implant from the manufacturer and who is therefore in the best position to read any warnings contained in the product packaging. In this respect, breast implants are, in my view, analogous to prescription drugs, where the patient places primary reliance for information on the judgment of the surgeon, who is a "learned intermediary", and not on the manufacturer; see *Buchan* [35 C.C.L.T. 1 at 16]. They are not analogous to oral contraceptives, with respect to which many American courts have recently imposed a direct duty to warn, because direct warnings from manufacturers of breast implants are simply not feasible given the need for intervention by physicians; see *Mac Donald v. Ortho Pharmaceutical Corp.*, 475 N.ze. 2nd 65 (Mass., 1985), at p. 70, ...; *Buchan* [35 C.C.L.T. at 16 f.]. In this respect, I observe that it is not, and has never been, Dow's practice to send warnings concerning their breast implants directly to patients. Although Dow includes product information with its implants, the implants are sold only to doctors or medical establishments, who are expected to pass this information on to their patients. In light of this fact, I conclude that a manufacturer in Dow's position can discharge its duty to the ultimate consumer by giving the treating surgeon clear, complete and current information concerning any general and specific risks that arise from the ordinary use of the product.[664]

In *Murphy v. St. Catharines General Hospital* where the operation of a machine used in an intravenous operation was in question, the court stated:

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[662] Breast implants in *Hollis*.
[663] *Murphy v. St. Catharines Gen. Hospital*, [1964] 1 O.R. 239, 41 D.L.R. (2d) 697.
[664] *Hollis* at 25.

> This instrument was never intended or expected to be handled by a member of the public but only by doctors or under their close supervision or instruction ... Here there was a warning to the hospital whose responsibility it was to use the device only through properly trained and supervised personnel. This is sometimes called the "learned intermediary" rule... .[665]

All these cases provide examples where the "learned intermediary" rule was applicable. In them the rule enabled the manufacturers to satisfy the duty to the consumer by providing the warning to a learned intermediary as a professional. That professional might in various circumstances be a physician, or a hospital represented by one, a pharmacist[666] or even a hairdresser.

In such cases the manufacturer may expect the professional to interpose his judgment and reason as to whether he is going to use the product or not; and therefore he may satisfy the duty to warn the ultimate consumer by warning the learned intermediary of the risk inherent in any use of the product.

In conformity with this approach, the "learned intermediary" rule has been applied to other cases of pharmaceutical products. Besides those products, like breast implants, that are never actually sold directly to the consumer, the rule comes into play for prescription drugs. The reason for adopting the "learned intermediary" rule in this context, with the consequence that the manufacturer can discharge his duty to the ultimate consumer by only warning the prescribing physician, is the idea that a physician, as a professional, will normally be involved in the decision to take or not to take the particular drug, because it is only available by prescription. It is also based on the hypothesis that the patient is placing primary reliance on the professional advice of the "learned intermediary", not on

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[665] [1964] 1 O.R. 239 at 254.

the manufacturer, because it is the prescribing physician who makes the diagnosis and with it the judgment considering the patient's particular needs, combined with knowledge about the recommended medical products.[667] For these reasons a warning given only to the prescribing physician has been considered sufficient. As a result, the manufacturer does not in such cases have to provide the consumer directly with the warning.

In *Buchan v. Ortho Pharmaceutical*, Robins J. A. confirmed these arguments by way of an *obiter dictum* in a unanimous decision, as follows:

> I do not quarrel with the general proposition advanced by the defendant that where prescription drugs are concerned, the manufacturer's duty to warn is limited to an obligation to warn prescribing physicians of potential dangers that may result from the drug s use. This special standard represents an understandable and sensible exception to the well-recognized common law principle of tort liability that the manufacturer of a product has a duty to warn users of dangers inherent in the use of the product.[668]

This doctrine, however, has given rise to the question[669] of whether the rationale relied on to support this exception, with respect to prescription drugs generally, can be justified in the case of long term prescription drugs, such as oral contraceptives? Until recently there

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[666] There are drugs that do not need to be prescribed by a physician. but can only be purchased from a pharmacist as a professional. He would then be a learned intermediary.

[667] *Hollis* at 23, *Buchan* at 15; both courts adopted the arguments from the American case *Reyes v. Wyeth Laboratories* 498 F. 2d 1264. cert. den. 419 U.S. 1096 (1974); in *Buchan* it is stated as follows:

> The rationale for the exception is that prescription drugs are more likely to be complex medicines, esoteric in formula and varied in effect and, by definition, are available only by prescription. The prescribing physician is in a position to take into account the propensities of the drug and the susceptibilities of his patient. He has the duty of informing himself of the benefits and potential dangers of any medication he prescribes, and of exercising his independent judgment as a medical expert based on his knowledge of the patient and the product. In taking the drug, the patient is expected to, and it can be presumed does, place primary reliance on hid doctor's judgment. In this relationship, the prescribing physician is said to act as a learned intermediary between the manufacturer and the ultimate consumer. Thus, while the general rule is that manufacturers of drugs have a duty to warn users of known dangers in the use of their products, manufacturers of prescription drugs, because of the intervention of the learned intermediary, have a duty to warn only prescribing physicians.

[668] *Buchan* at 36.

[669] *Buchan* at 36/37.

had not been any decisions dealing specifically with oral contraceptives in Canada or England. The court in *Buchan v. Ortho Pharmaceutical* referred to a new doctrinal tendency that could be observed in several state courts in the United States, which had concluded that oral contraceptives needed to be distinguished from other prescription drugs. The result was that the learned intermediary rule had been displaced by the requirement of a direct warning to the consumer, combined with a warning provided to the physician.

The reason for developing such an approach was mainly the absence of those particular relational characteristics, normally resulting from the high standard of medical supervision in decisions related to the usage of a drug and the duration of treatment with the drug, which justify an exemption to that general rule and which allow the manufacturer to discharge his duty towards the consumer by only warning the physician. The distinction from other prescription drugs was especially seen in the heightened participation typically shown by users of oral contraceptives in the process of choice, the relatively easy feasibility of giving direct warnings to the consumer, the limited participation of the physician in the long-term duration of prescriptions, and the often scanty medical supervision of their use. In this case the learned intermediary rule was held inapplicable, on the basis that the particular circumstances involved in the decision to take an oral contraceptive demanded that the manufacturer be obliged to warn the consumer in both the above-considered ways: directly by including a warning on the pill package and in addition indirectly by warning physicians of dangerous side-effects and any inherent risks in the drug. Robins J.A. continued, by way of *obiter*:

> There can be little doubt that oral contraceptives have presented society with problems unique in the history of human therapeutics. At no time have so many people taken such potent drugs voluntarily over such a protracted time for an objective other than the control of disease. This has introduced a novel element in the doctor-patient relationship. As the advisory committee pointed out, "in prescribing these drugs, the doctor is usually acting neither to treat nor to prevent a disease. He is prescribing for socioeconomic reasons". Furthermore, unlike the selection of an appropriate drug for the treatment of illness or injury where patient involvement is typically minimal or non-existent, consumer demand for oral contraceptives prompts their use more often than doctor's advice. The decision to use the pill is one in which consumers are actively involved; more frequently than not, they have made the decision before visiting a doctor to obtain a prescription.
> For these reasons, (as well as those stated in *Mac Donald v. Ortho Pharmaceutical Corp.*, supra, which I quoted earlier,) I am of the view that oral contraceptives bear characteristics distinguishing them from most therapeutic, diagnostic and curative prescription drugs. The rationale underlying the learned intermediary rule, in my opinion, does not hold up in the case of oral contraceptives. Manufacturers of this drug should be obliged to satisfy the general common law duty to warn the ultimate consumer as well as prescribing physicians.[670]

For the sake of completeness the reasoning of the Supreme Judicial Court of Massachusetts in *MacDonald v. Ortho Pharmaceutical Corp.*[671], referring to the vastly different character of the contraceptive pill as distinct from the general group of prescription drugs, should be pointed out because the Ontario Supreme Court, in *Buchan v. Ortho Pharmaceutical*, made overt reference to this decision in support of its position[672], as instructive and pertinent to this issue. In that case the majority of the court said:

> The oral contraceptive thus stands apart from other prescription drugs in light of the heightened participation of patients in decisions relating to use of "the pill"; the substantial risks affiliated with the product's use; the feasibility of direct warnings by the manufacturer to the user; the limited participation of the physician (annual

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[670] *Buchan* at 36 f.
[671] *475 N.E. 2d 65, cert. den. 106 S. Ct. 250 (Mass., 1985) at p. 70.*
[672] *Buchan* at 16:
> The reasoning which promoted these courts to hold the learned intermediary rule inapplicable to birth control pills is clearly articulated in the decision of the Supreme Judicial Court of Massachusetts in *MacDonald v. Ortho Pharmaceutical Corp.*, 475 N.E. 2d 65, cert. den. 106 S. Ct. 250 (Mass., 1985).

> prescriptions); and the possibility that oral communications between physicians and consumers may be insufficient or too scanty standing alone fully to apprise consumers of the products dangers at the time the initial selection of a contraceptive method is made as well as at subsequent points when alternative methods may be considered. We conclude that the manufacturer of oral contraceptives is not justified in relying on warnings to the medical profession to satisfy its common law duty to warn, and that the manufacturer's obligation encompasses a duty to warn the ultimate user. Thus, the manufacturer's duty is to provide to the consumer written warnings conveying reasonable notice of the nature, gravity, and likelihood of known or knowable side effects, and advising the consumer to seek fuller explanation from the prescribing physician or other doctor of any such information of concern to the consumer.[673]

These explanations lead to the following conclusion: The question as to whom the pharmaceutical manufacturer has to address his warning, so as to satisfy his duty to warn the ultimate user of the potential dangers inherent in his product, and thereby escape liability, has to be answered in a particularised manner. The cases involving this issue can basically be divided into four different categories.

The first embraces so called "over the counter drugs", like pain-relieving anodynes, *e.g.*, Aspirin, Tylenol. The warning needs to be addressed directly to the ultimate consumer, who is able to buy the drug without professional advice, like any other ordinary product sold in stores to their customers. No exception is permitted to the general rule. The second group consists of non-long-term prescription drugs, where the consumer cannot get the product without going through two sets of professional hands, the doctor's and the pharmacist's. Here the learned intermediary rule is applicable, because of the intervention of the prescribing physician and the professional intermediate examination and supervision of the pharmacist. Under these circumstances the informational duty can be satisfied indirectly by providing the prescribing physician with the required warning.

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[673] *Buchan* at 16.

In contrast to this, the cases of long-term-prescription drugs, such as the contraceptive pill[674], form a third group. Proceeding on the assumption that the learned intermediary doctrine has been displaced, a direct warning to the drug user is required and should be secured by an additional warning given to the prescribing physician.

The fourth and last category covers pharmaceutical products that are actually never sold directly to the consumer but obtained by the physician, who brings the product into contact with the patient's body, like breast implants and other prosthetic devices, vaccinations, artificial inseminations and blood transfusions.

This last category is different because the nature of the product is such that the consumer will not realistically receive a direct warning from the manufacturer before using it, because neither the product nor the packaging are placed directly into the hands of the ultimate consumer. It is the surgeon, physician or the medical establishment, not the consumer, who obtains the product and who is therefore in the best position to read any warnings contained in the product packaging or given on the package label.[675] This is clearly a case where the rationale for the learned intermediary rule is applicable, as the consumer himself does not buy the product but receives it through professional intervention with his treatment. Here preliminary intermediate inspection and examination is invariably presupposed and can be anticipated; in other words: it is the typical situation in practice that the ultimate consumer receives his information from the learned intermediary. Therefore it might not even be expected, demanding from the manufacturer a duty to address a warning separately to the patient. Although it would be

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[674] And perhaps insulin? We cannot be sure on the basis of *Buchan*.
[675] *Hollis* at 25.

within the bounds of imagination that the manufacturer would supply the product package with an extra warning addressed to the patient, as is done in the German jurisdiction in cases of vaccination, such an approach would be impractical in real life, and unnecessary too, if the package insert, addressed to the learned intermediary, is adequate and the learned intermediary is in compliance with his duty. This means the manufacturer is allowed to give an indirect warning to the ultimate consumer by providing the treating physician or the medical institution with the necessary product information, because one can expect a shift of direct duty to the learned intermediary to pass this information on to the patient.[676]

Nevertheless, it must be acknowledged that mandatory direct warnings to consumers, through patient package inserts, would probably provide greater consumer control of information, as well as a basis for asking questions of physicians.[677]

In contrast to the Canadian law, German law concerning pharmaceutical products does not provide or operate with a "learned intermediary" rule to regulate the issue of "who needs to be addressed with the necessary product information?". The German law determines the medium of necessary product information by statutory regulations, such as in the case of "finished" drugs in regulations of the Pharmaceutical Product Act about labelling, package inserts and expert information. The product's labelling and package insert provides a direct source of the necessary product information, user instructions and warnings for consumer, but also for physicians and pharmacists. In case of long term

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[676] *Hollis* at 25.
[677] Peppin, at 516.

prescription the consumer receives a new package insert each time a new drug package is purchased. Besides that the regulations about expert information provide for an additional source of information reconciled to the experts' needs. The separation of package insert and expert information allows one to adjust the information in contents, use of language and presentation to the different needs of consumers and professionals. Where the pharmaceutical product does not actually get into the consumers' hands, because it is applied or used by the learned expert only, such as vaccinations, the patient receives the information needed and sometimes additionally the product's package insert from his treating physician. In this way both systems aim for the best consumer protection and are based on the same legal principle, namely that the manufacturer generally owes a duty to inform, instruct and warn the consumer directly.

The comparison reveals that both systems follow the same demands and aim for the same results, but to this end have developed and established slightly different legal ways for its achievement. This is obviously due to their distinct legal methodology: on the one hand statutory provisions, which allow for regulation regarding the circulation of information in any anticipated way it might be needed; on the other, reliance upon the ongoing and piecemeal development of judicial doctrine, on a case-by-case basis.

C. Causation

This section deals with requirements of causation and damage. Once the plaintiff has convinced the court that the defendant has breached his duty of care, as by the omission to circulate sufficient product information, instructions for use or necessary warnings, and

that he has suffered subsequent damage, the plaintiff has to prove a causal link between the negligent act and his injury, which will count as the damage in the pharmaceutical product related cases, as a vital element of negligence. The injury must result from or be attributable to the act of the duty breaker. The test of causation is: "If the injury would not have occurred but for the defendant's negligence", then this conduct becomes a cause of the injury. Asked from a different perspective, it becomes "What would have happened to this plaintiff if the breach of the duty had not occurred?". The related question arising hereunder is: "What does the plaintiff have to avert?" in order to convince the court in his favour, *i.e.*, "Which is the appropriate test?"; followed by the question: "What does the complainant have to prove?" to succeed with his claim against the pharmaceutical manufacture defendant, *i.e.*, "What must the plaintiff prove?".

I. General causation principles

To better understand the specific problems that occur, in the context of a claim by the injured user of a pharmaceutical product against the manufacturer who allegedly breaches a duty of care, an initial distinction must be made between cases where the product itself was defective and those where the manufacturer is accused of having breached the duty to warn the ultimate user about the inherent risks of the pharmaceutical product. This is because in relation to defective products the negligent conduct that caused the damage is generally an action of the manufacturer, whereas in duty to warn cases it is an omission that might have caused the plaintiff's injury. The difficulty here is to find a causal connection on hypothetical grounds.

Generally, causation is established where the plaintiff proves to the civil standard, *i.e.*, on a balance of probabilities, that the defendant's conduct caused or contributed to the injury.[678] The general, but not conclusive, test for causation is the "but-for" test. It requires the plaintiff to show that the injury would not have occurred but for the negligence of the defendant.[679] In some circumstances, where the "but-for" test is unworkable or productive of obvious injustice, the courts have recognised that causation is established where the defendant's negligence "materially contributed" to the occurrence of the injury.[680] This shows that the causation test is not to be applied too rigidly. Causation need not be determined with scientific precision, as it is "essentially a practical question of fact which can best be answered by ordinary common sense".[681] This interpretation leaves room for establishing adequate results where various causation problems might appear in special circumstances in different cases.

Technically, as a matter of law in any negligence action, the burden of proof throughout the case is on the plaintiff. Although the burden of proof remains with the plaintiff, in some circumstances an inference of causation may be drawn from evidence without positive scientific proof. In practice, as the case proceeds, the evidential burden of proof will shift from plaintiff to defendant, requiring the latter to come up with a good

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[678] *Athey v. Leonati*, (1997) 31 C.C.L.T. (2nd) 113 (S.C.C.), at p. 119; *Snell v. Farrell*, [1990] 2 S.C.R. 311; *Mc Ghee v. National Coal Board*, [1972] 3 All E.R. 1008 (H.L.).
[679] *Athey v. Leonati*, *supra*, at p. 120; *Horsley v. MacLaren*, [1972] S.C.R. 441.
[680] *Athey v. Leonati*, *supra*; *Myers v. Peel (County) Board of Education*, [1981] 2 S.C.R. 21: *Bonnington Castings Ltd. V. Wardlaw*, [1956] 1 All E.R. 615 (H.L.), *Mc Ghee v. National Coal Board*, *supra*.

explanation and show that the associated facts of another causal sequence seem plausible. In these cases the evidential burden of proof can shift to and fro.

II. Special principles in cases of breach of the duty to warn

The breach of the duty to warn raises the following question of causation-in-fact:

Did the manufacturer's breach of the duty to warn cause the consumer's injury?

Such would be so, if the injury would not have occurred but for the manufacturer's negligence, in not warning the drug user about the potential risks of the product. The question is: what would have happened to this plaintiff if the breach of the duty had not occurred? Put another way: would the plaintiff have consented or refused to take the drug if he had been properly warned of the risks?

In order to succeed in the action the plaintiff has to show and prove that, if the requisite information had been given, he would have refused to use the product and that that refusal would have avoided the injury.

1. Legal standard of causation in medically related cases: the court's tools for determination of causation; or, how does the plaintiff have to prove causation?

The problem is the court's task to find the appropriate standard determining causation on the grounds of hypothetical causal circumstances, *i.e.*, whether the plaintiff would have refused to use the drug, if he had been given the required warning issued by the manufacturer? Special problems may be seen as arising out of the situation, in that the

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[681] Per Sopinka J. in *Snell v. Farrell, supra*, at p. 328 quoting from Lord Salmon in *Alphacell Ltd. V. Woodward*, [1972] 2 All E.R. 475 at 490 (H.L.).

drug user, often suffering severe physical damage, will subsequently with the benefit of hindsight be convinced that he would have refused consent to the drug use. On the other side there will be the manufacturer-defendant, opposing the use of such a subjective viewpoint and defending himself by saying that the plaintiff, were he put back into the starting position of the risk-benefit evaluation, would decide to take the product again, expecting that the results hoped for from using the drug would occur. This inevitably leads to a consideration of those other situations in which courts have had to deal with a similar problem examining causation-in-fact. This has occurred in so-called "informed consent" cases in the sphere of medical malpractice, cases which arose out of doctor-patient relationships, where the doctor's performance resulted in a lawsuit from the patient's side. In these cases the patient subsequently claims that he had not given a valid consent to the doctor's particular treatment; rather, he would not have consented or would have refused to undergo the treatment, if he had only been given the proper disclosure of information about those known risks associated with the product's use, risks that have subsequently now materialised in his case.

The causation problems involved in these informed consent cases are worthy of consideration in this thesis as offering possible approaches or starting points which might be useful in our present case constellation.[682] It is true that this litigation is based on

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[682] Corresponding with the German approach, such a relevant connection or relation between the two constellations was also realised by the Supreme Court of Canada, in the referral, at the beginning of the judgment on the causation issue in *Hollis* at 33, to the situation dealt with in *Reibl*, as well as the Ontario Court of Appeal in the judgment in *Buchan*. The necessity to compare the different cases, *i.e.*, pharmaceutical product liability and medical malpractice, follows additionally out of the fact, that the courts in different instances have used the various approaches of the "informed consent" cases for different standards for proving causation-in-fact. As will be shown later on, these were originally developed in the "informed consent" cases, which means in cases between physicians and patients. *E.g.*, in *Hollis*, the Court of Appeal based its decision on its application of the modified -objective test, identical to that favoured in

doctor-patient relationships, whereas the substance of this thesis deals with issues rising out of manufacturer-consumer relationships. Nevertheless, the causation issues dealt with in "informed consent" cases have consistently been included in grounds for judgments in pharmaceutical product liability cases, whenever the court came to determine the causal connection between the failure to warn and the loss claimed to be suffered therefrom.

The Canadian courts have consistently had recourse to comparisons between doctor-patient relationships, where there has been a failure to communicate information, and manufacturer-consumer relationships, where there has been a similar failure.[683] The reasons for this persistent analogy are not difficult to guess. In both contexts the same fundamental right of the patient or consumer - the right to have knowledge sufficient for self determination in one's health care[684] - is at issue. While the courts are understandably committed to a measure of self-consistency in determining the content of the duty of care, they have, as we shall see, felt obliged to draw distinctions between them in the matter of causation. This is done, just as in the German litigation on this matter, in deference to the different dynamics of the relationships between the parties involved.

"informed consent" litigation, whereas the majority of the Supreme Court found the subjective test appropriate for product liability cases.

[683] *E.g.*, *Hollis* at 21 f., recently *Arndt v. Smith* [1997] 35 C.C.L.T. (2nd) 233 (S.C.C.) at 245ff., where reference was made in the converse situation.

[684] Laskin, C.J.C. in: *Hopp v. Lepp*, [1980] 2 S.C.R. 192 at 196: "The right of a patient to decide what, if anything, should be done with his body"; or La Forest, J., in Hollis at 21: "The doctrine of "informed consent" dictates that every individual has a right to know what risks are involved in undergoing or foregoing medical treatment and a concomitant right to make meaningful decisions based on a full understanding of those risks."

a. Causation test in "informed consent" cases; doctor-patient relationships

The question presented to the court in "informed consent" cases, *i.e.*, doctor-patient relationships, has been: how to determine whether the patient would have actually chosen to decline the doctor's proposed treatment if he had been properly informed of the risks involved?

The modern approach on this issue was established in *Reibl*,[685] where the Supreme Court set out basic principles for assessing causation issues and delineated different standards expressed through different tests that can be applied for determining causation in the particular case: the subjective test, the objective test and the modified objective test.

In *Reibl*, Laskin, C.J.C. referred to an article[686] regarding the same issue:

> Since proximate causation exists only if disclosure would have resulted in the patient's foregoing the proposed treatment, a standard must be developed to determine whether the patient would have decided against the treatment had he been informed of its risks. Two possible standards exist: whether, if informed, the particular patient would have foregone treatment (subjective view); or whether the average prudent person in [the] plaintiff's position, informed of all material risks, would have foregone treatment (objective view). The objective standard is preferable, since the subjective standard has a gross defect: it depends on the plaintiff's testimony as to his state of mind, thereby exposing the physician to the patient's hindsight and bitterness....[687]

According to the Court, there are different possibilities open for the proof of causation in the doctor-patient cases: a subjective testimony of the plaintiff, saying whether or not he would have decided to undergo the procedure that caused his harm, if a proper disclosure

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[685] *Reibl* [1980] 2 S.C.R. 880 at 884 f., 14 C.C.L.T. 1, D.L.R. (3d) 1, 33 N.R. 361; also see *Arndt v. Smith*, (1997), 35 C.C.L.T. (2nd) 233 at 238 f. "*The starting point for this question must be Reibl v. Hughes*".

[686] (1973), 48 New York University Law Review (N.Y.U.L. Rev.) 548 at 550, entitled "*Informed Consent - A Proposed Standard for Medical Disclosure*".

of information had been given to him; secondly, a strict objective judgment found by the court, based on testimony of professional witnesses, determining the decision a reasonable person in the patient's medical position would have made; and last, a modified objective assessment, determining what a reasonable person in the patient's particular position, including attitudes, values, tastes and belief-systems, as well as the material circumstances of the particular patient, would have done. In this influential decision in *Reibl*, the court analysed and discussed the pros and cons of each test, expressing a different standard for assessing causation in the particular cases of "informed consent". As a subjective and a purely objective test were subject to criticism, the Court chose a modified objective test as the only appropriate one in doctor-patient relationships.

The subjective test was rejected[688] and criticised[689] for placing undue emphasis upon the plaintiff's evidence, not having consented to the procedure under the circumstances mentioned above. Arguably, the test places too much weight on potentially unreliable testimony by the patient, influenced by the wisdom of hindsight, to the disadvantage of the physician, resulting in the causation issue invariably being resolved in the patient's favour.

In *Reibl* Laskin C.J.C. elaborated these concerns, as follows:

> It could hardly be expected that the patient who is suing would admit that he would have agreed to have the surgery, even knowing all the accompanying risks. His suit

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[687] *Reibl* at 897 f.
[688] Laskin, C.J.C. for a unanimous court in *Reibl* at 898.
[689] Osborne in: Barney Sneiderman, John C. Irvine & Philip H. Osborne, *Canadian Medical Law*, 2nd ed. (Toronto: Carswell, 1995) at 61; hereafter cited as: Osborne.

> would indicate that, having suffered serious disablement because of the surgery, he is convinced that he would not have permitted it if there had been proper disclosure of the risks, balanced by the risks of refusing the surgery. Yet, to apply a subjective test to causation would, correlatively, put a premium on hindsight, even more of a premium than would be put on medical evidence in assessing causation by an objective standard.[690]

In a manner similar to the subjective test, an objective approach, based on the actions of a hypothetical reasonable person in the patient's medical position, has its deficiencies. Even though it would avoid putting an inappropriate emphasis on the plaintiff's testimony, a strict objective test might result in undue emphasis being placed on the medical evidence relating to the advisability of the treatment, in the light of inherent risks and anticipated benefits.[691] If the information provided by the physician was medically justifiable in the patient's medical situation, and therefore in the interests of the plaintiff, the chances of proving causation become slim because, according to a test which defers completely to contemporary medical authority, a reasonable person would usually follow the advice of his physician, whether or not the requisite disclosure of information was made. Satisfying the Court that the hypothetical reasonable patient would have not consented under the given circumstances becomes an onerous burden for the plaintiff-patient.[692]

Laskin C.J.C. discussed his paramount concerns about a purely objective test:

> ... a vexing problem raised by the objective standard is whether causation could ever be established if the surgeon has recommended surgery which is warranted by the patient's condition. Can it be said that a reasonable person in the patient's position, to whom proper disclosure of attendant risks has been made, would decide against the surgeon's recommendation that it be undergone? The objective standard of what a reasonable person in the patient's position would do would seem to put a

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[690] *Reibl* at 897 f.
[691] Osborne, *supra* at footnote 689.
[692] Osborne, *supra* at footnote 689.

> premium on the surgeon's assessment of the relative need for the surgery and on supporting medical evidence of that need. Could it be reasonably refused?[693]

In order to escape the disadvantages of either of these tests the Supreme Court balanced the objective and subjective factors and combined them in the so-called modified objective test, in order to determine whether the failure to disclose actually caused the harm of which the plaintiff complains. This requires that a court consider what a reasonable patient in the circumstances of the plaintiff would have done if faced with the same situation. This includes a consideration of any particular concerns of the patient and any special considerations affecting the particular patient in his decision about the proposed treatment.[694] Herein lies the difference from the strict objective test, which would only refer to the hypothetical ordinary prudent patient in the same medical situation as the plaintiff, by neglecting any particular circumstances involved which might be affecting that individual's life or potentially influencing his thoughts.

Laskin opted for the modified objective test as follows:

> I think it is the safer course on the issue of causation to consider objectively how far the balance in the risks of surgery or no surgery is in favour of undergoing surgery. The failure of proper disclosure pro and con becomes therefore very material. And so too are any special considerations affecting the particular patient. For example, the patient may have asked specific questions which were either brushed aside or were not fully answered or were answered wrongly. In the present case, the anticipation of a full pension would be a special consideration, and, while it would have to be viewed objectively, it emerges from the patient's particular circumstances. So too, other aspects of the objective standard would have to be geared to what the average prudent person, the reasonable person in the patient's particular position, would agree to or not agree to, if all material and special risks of going ahead with the surgery or foregoing it were made known to him. Far from

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[693] *Reibl* at 898.
[694] *Arndt v. Smith* at 250.

> making the patient's own testimony irrelevant, it is essential to his case that he puts his own position forward.
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> The adoption of an objective standard does not mean that the issue of causation is completely in the hands of the surgeon. Merely because medical evidence establishes the reasonableness of a recommended operation does not mean that a reasonable person in the patient's position would necessarily agree to it, if proper disclosure had been made of the risks attendant upon it, balanced by those against it. The patient's particular situation and the degree to which the risks of surgery or no surgery are balanced would reduce the force, on an objective appraisal, of the surgeon's recommendation. Admittedly, if the risk of foregoing the surgery would be considerably graver to a patient than the risks attendant upon it, the objective standard would favour exoneration of the surgeon who has not made the required disclosure. Since liability rests only in negligence, in a failure to disclose material risks, the issue of causation would be in the patient's hands on a subjective test, and would, if his evidence was accepted, result inevitably in liability unless, of course, there was a finding that there was no breach of the duty of disclosure. In my view, therefore, the objective standard is the preferable one on the issue of causation.
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> In saying that the test is based on the decision that a reasonable person in the patient's position would have made, I should make it clear that the patient's particular concerns must also be reasonably based; otherwise, there would be more subjectivity than would be warranted under an objective test. Thus, for example, fears which are not related to the material risks which should have been but were not disclosed would not be causative factors. However, economic considerations could reasonably go to causation where, for example, the loss of an eye as a result of nondisclosure of material risk brings about the loss of a job for which good eyesight is required. In short, although account must be taken of a patient's particular position, a position which will vary with the patient, it must be objectively assessed in terms of reasonableness.[695]

This legal approach was reaffirmed in *Arndt v. Smith*[696], a case where a "modified objective" test was applied for determining causation when a doctor was sued by his patient for medical malperformance.

In summary: the Canadian litigation results in the following question when considering the causation issue in cases vis-à-vis the physician: would the plaintiff or more accurately

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[695] *Reibl* at 898-900.
[696] (1997), 213 N.R. 243, at pp. 245 ff.[also: (1997) 35 C.C.L.T. (2nd) 233].

"a reasonable patient in his medical position", if properly warned, have consented or refused to undergo the treatment?

Before this reasoning is examined in regard to the special situation and problems dealt with in this thesis, namely a plaintiff's relationship vis-à-vis the pharmaceutical manufacturer, we may glance at the German case law which, in a way quite similar to the Canadian, considers the patient-physician relationship when contemplating this matter. The problem in both jurisdictions is the same, namely: how can the law assist the injured plaintiff in showing causation regarding a hypothetical situation to the satisfaction of the court? However, the reason for considering the litigation on patient-physician relationships in this context is rather different in German courts. The German litigation does not address the problem of finding the appropriate test for proving causation. Due to Germany's different procedural law, this problem does not occur in quite that way. The question of causation is open to be proved by the plaintiff's testimony. It is then on the part of the court to assess this testimony objectively in terms of reasonableness in the frame of what is called the consideration of the evidence (*Beweiswuerdigung*). The court will base its judgment on the decision that a reasonable person in the patient's position would have made by weighing *inter alia* the patient's particular concerns relevant under the given circumstances; and so will basically come to the same results as a Canadian would.

The debate arising in German jurisdictions when judging a patient's claim against the manufacturer, however, has rather been due to the fact that the plaintiff's situation in patient-physician relationship litigation was eased by reversing the burden of proof. If the injured patient is able to show that his physician has either failed in his medical

performance, or violated his duty to give full disclosure about a particular risk involved in his treatment, as by the administration or prescription of a pharmaceutical product, it is on the treating physician to bring forward evidence showing that his failure did not contribute to or cause the injury. In light of that, the distinction from the Canadian law, which concerns the application of a subjective test versus an objective one for determination of causation, is obvious. The question asked in German courts is, whether to allow any alleviating mechanism for the plaintiff's liability claim against the manufacturer by reversing the burden of proof regarding causation, just as in cases against a physician.

b. Eligible tests of causation in "duty to warn" cases; manufacturer-consumer relationship

The question to be answered with respect to the causation issue here is: which test is appropriate to apply when determining whether the loss claimed by the plaintiff was caused by the manufacturer's failure to give an adequate warning of the risk associated with the product's use?.

Should the court apply a modified-objective test, such as: would the plaintiff or more accurately "a reasonable consumer in his position", if properly warned, have consented to or refused taking the drug? Or should the judgment be based on a subjective testimony of the injured consumer, answering what he himself would have done? Or is some entirely different test of causation called for in this context?

aa. Subjective test

Accordingly to this subjective approach, in a case against the manufacturer the plaintiff must prove that he would have refused to "consume" the product if he had been warned of the risks associated with it.

The Supreme Court of Canada applied such a test in *Hollis v. Dow*, referring to the decision made in *Buchan v. Ortho Pharmaceutical* by Robins, J.A. for the Ontario Court of Appeal, which had found the *Reibl* test, involving, as it had, objective factors, inappropriate in product liability cases. La Forest, J. for the majority of the Supreme Court stated:

> In my view, the rationale given by Robins J.A. for a subjective test is compelling and justifies the adoption of the subjective test in cases of this nature. The most serious concern raised by the application of the subjective test is that the plaintiff, with the benefit of hindsight, will always claim that she would not have used the product if she had been properly warned....
>
> Although the concern raised by Laskin C.J.C. is valid and should continue to be applied in doctor-patient relationships, in a suit against a manufacturer for failure to warn this concern can be adequately addressed at the trial level through cross examination and through a proper weighing by the trial judge of the relevant testimony. While this difference between the type of proof required in the two kinds of actions may seem anomalous, it is amply justified having regard to the different circumstances in which the relevant duties arise, and the consequent difference in the nature of these duties. As Robins J.A. intimated in Buchan, the duty of the doctor is to give the best medical advice and service he or she can give to a particular patient in a specific context. It is by no means coterminous with that of the manufacturer of products used in rendering that service. The manufacturer on the other hand, can be expected to act in a more self-interested manner. In the case of a manufacturer, therefore there is a greater likelihood that the value of a product will be overemphasized and the risk under-emphasized. It is, therefore, highly desirable from a policy perspective to hold the manufacturer to a strict standard of warning consumers of dangerous side effects to these products. There is no reason, as in the case of a doctor, to modify the usual approach to causation followed in other tortious actions. Indeed the imbalance of resources and information between the manufacturer and the patient, and even the doctor, weighs in the opposite direction. Moreover, it is important to remember that many product liability cases of this nature will arise in a context where no negligence can be attributed to a doctor. It would appear ill-advised, then, to distort the rule that is appropriate for claims

> against a manufacturer simply because of an apparent anomaly that results in cases where a doctor is also alleged to have been negligent.[697]

The arguments given in support of this subjective approach basically refer to the fact that the present case is in the context of product liability and is therefore treated as such. That necessitates consideration of the essentially self-interested position to be expected of a manufacturer striving to promote a product. Neither the fact that a physician as an intermediary may be involved in the decision to use a product, nor the circumstances arising out of the triangular relationship involving a doctor, persuaded the court to apply a modified-objective test for determining causation. The standard provided by that test was, according to the court, developed under exceptional circumstances only for the special situation dealt with in doctor-patient "informed consent" cases. The purpose of establishing this exception was to adjust the disadvantage of a subjective testimony, coloured with the possibly inherent unreliability of the plaintiff's self-serving assertion, caused by bitterness and hindsight, with the more objective approach, which also takes into account the medical evidence relating to the advisability of the treatment in the balance of inherent risks with anticipated benefits. The reasoning here turns against any such mollification of the ordinary tort principles of causation, developed to accommodate the special role of the doctor.[698]

Upon a review of the arguments given in German judgments and scholarly opinions, it turns out that the idea of easing the plaintiff's claim situation, by reversing the burden of

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[697] *Hollis* at 34 f.
[698] *Ibid.*

proof concerning the causal connection between the manufacturer's failure to warn and the plaintiff's injury, has been largely denied for essentially the same reasons.

bb. Modified objective test, alias *Reibl*-test

Judicial opinions have also been heard in recent years, dissenting from or challenging the prevailing approach just mentioned, favouring adoption of the modified-objective, *Reibl*-type causation test in manufacturer-consumer litigation, too.

A modified-objective test applied in a claim against the manufacturer-defendant would ask hypothetically, what a reasonable consumer in the particular situation of the plaintiff would have done?

Contrary to the Supreme Court's ultimate decision, Prowse J.A. for the Ontario Court of Appeal in *Hollis*, held this test applicable, asking: whether a reasonable woman in the position of the plaintiff would have agreed to the breast implant surgery if she had been aware of the risks, albeit small, of rupture?[699]

Convinced of the appropriateness of the objective standard, based on the reasoning in *Reibl*,[700] mentioned above, she interestingly reached the same conclusion at the end of this case by applying the "reasonable woman" test as she would have reached by applying the subjective standard, namely that there was a causal connection between the manufacturer's failure to warn and the injury suffered by the plaintiff.[701]

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[699] (1993), 16 C.C.L.T. (2nd) 140 at 162.
[700] *Ibid.* at 161 f.
[701] *Ibid.* at 164.

Likewise, Sopinka, J. in a dissenting opinion in *Hollis*[702], explaining the familiar advantages of a modified-objective approach to causation, also rejected the subjective test solely based on the plaintiff's testimony and instead used the *Reibl* test, which he found equally applicable vis-à-vis a manufacturer.[703] In fairness one can only say that this opinion is aimed at the situation where the learned intermediary rule is applicable, as was the case in *Hollis*.[704] It is not clear if this is his opinion in general, in respect of all kinds of pharmaceutical product liability cases. Obviously referring to prescription drug situations, *i.e.*, cases where doctors are necessarily involved in the decision to take certain medical products, he further stressed that he saw no reason why the test for determining the same issue should be different for the physician and the manufacturer. In this connection he also questioned the justification of the argument that a stricter standard can be applied to the latter. Regarding subjective testimony as inherently unreliable, because of the self-serving nature of the plaintiff's assertion, he pointed out that it is not simply a question as to whether the plaintiff is believed. He acknowledged that a plaintiff may be perfectly sincere in stating that he would not have consented to the procedure, but this would not be a statement of fact that, if accepted, should conclude the matter. In Sopinka, J.'s view, this is only the plaintiff's opinion about what in hindsight he believes he would have done, in a situation which never occurred. As such, the opinion may be honestly given, he argues, but must not be accepted unreflectively or uncritically by the court. He continues his judgment:

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[702] *Hollis* at 43 ff.
[703] *Hollis* at 45 f.

> In evaluating the opinion, the trier of fact must discount its probity not only by reason of its self-serving nature, but also by reason of the fact that it is likely to be coloured by the trauma occasioned by the failed procedure. For this reason, the most reliable approach in determining what would in fact have occurred is to test the plaintiff's assertion by reference to objective evidence as to what a reasonable person would have done.[705] (emphasis in original)

Sopinka asks: "What would really have happened?" or "What would really be (have been) the plaintiff's decision?"

He suggests that testimony be taken of what the plaintiff thinks he would have done; but he does not treat this assertion as conclusory and thus would treat objective evidence in the same way. Reflecting on that, the plaintiff's testimony would be tested against the objective evidence, of what a reasonable person would have done. This means it is neither a (modified-) objective nor a subjective test that is to be used. It is rather that the courts are urged to listen to what the plaintiff has to say, but not necessarily follow, without also putting that alongside the objective evidence.[706] This in fact comes close to what is practiced in German courts.

If at this juncture we compare the two legal systems: both the Canadian and the German case law look to the situation dealt with in doctor-patient relationships. The motivation for this consideration, however, may be slightly different, for while the Canadian courts try to find the right test for determining causation, the German courts consider whether to ease the plaintiff's claim situation concerning proof of causation. Both systems draw a

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[704] *Hollis* at 47.
[705] *Hollis* at 45.
[706] This also corresponds with Laskin, C.J.C.'s statement in *Reibl* at 900: That the patient's testimony is essential, but "it must be objectively assessed in terms of reasonableness".

firm distinction with the manufacturer-consumer relationship, and in the final analysis deny the application of any legal regime particularly developed for the special situation that involves a physician and his patient.

In the end the consideration of evidence regarding proof of causation is determined similarly with reference to objective components in both Canadian and German courts. This permits the conclusion that the results will not essentially vary in comparable cases between either legal system.

2. Various causation issues involved in pharmaceutical product liability cases: what must the plaintiff prove?

Above questions concerning the legal standard of causation as discussed above, causation in drug liability cases involves consideration of various other problems. One is: which one of the tests is to be used to assess causation from the plaintiff's perspective in pharmaceutical product liability cases, when considering the manufacturer-consumer relationship which, under special circumstances, involves a physician as a "learned intermediary"? In this context, we must also discuss whether the distinction the Supreme Court of Canada is drawing, between doctor-patient "informed consent" cases and manufacturer-consumer failure to warn cases, is legally acceptable in so far as it makes a distinction between the applicable standards of causation? This involves two issues: What test is to be used? and - as it turns out - why different tests?

In this connection and in general, the plaintiff has to be looked at as a consumer in his action against the pharmaceutical manufacturer, just as in other product liability cases. But in the special situation of intervention by a "learned intermediary", the plaintiff plays

a double role. Besides being a consumer in his action vis-à-vis the manufacturer, he is also a patient vis-à-vis the physician. For the purpose of distinction, the consumer will be designated as a "patient" in the latter situation.

a. The appropriate test in manufacturer-consumer relationships

In order to succeed with his action against the pharmaceutical manufacturer, the plaintiff has to show a causal connection between the negligent conduct, which is in the present case the failure to warn, and the suffered damage. That is done by using the "but-for" test, *i.e.*, the plaintiff has to show whether the damage would or would not have occurred but for the defendant's negligence. This means, that the plaintiff has to convince the court that, if fully informed, he himself would have refused to take the pharmaceutical product. In his production of evidence, all means of proof are placed at the plaintiff's disposal including his own testimony. The plaintiff only has to prove, on a subjective test, what he would have done.[707] Canadian case law has so far proceeded on a subjective test of causation.[708] Thereby, the question of causation must be proved to the satisfaction of the court on the balance of probabilities.[709]

Robins J.A. argued in support of this view in *Buchan v. Ortho Pharmaceutical*. Though that case referred to the three-party situation (as in *Hollis*), where a physician is

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[707] Peppin, at 509.
[708] Conclusion drawn from *Reibl* quotation; "if Canadian case law has so far proceeded on a subjective test of causation, it is in Courts other than this one that such an approach has been taken.", [1980] 2 S.C.R. 880 at 897 f.
[709] Allen M. Linden, *Canadian Tort Law*, 5th ed. (Toronto: Butterworths, 1993) at 99.

interposed in the manufacturer-patient sequence, his substantive rationale endorses a general validity for the test applicable in manufacturer-consumer relationships:

> When a manufacturer's breach of the duty to warn is found to have influenced a physician's opinion as to the safety of a drug thereby contributing to the physician's non-disclosure of a material risk and the consumer's ingestion of the drug, the manufacturer is not entitled to require the injured consumer to prove that a reasonable consumer in her position would not have taken the drug if properly warned. At this juncture, the case stands on no different footing than the usual products liability case in which there is no question of the intervention of an intermediary, and should be treated as such. The manufacturer has put a product on the market without proper warning. The likelihood that the consumer will take the drug without knowledge of its potential risks is a foreseeable consequence of the breach of the duty to warn. Whether the particular consumer would have taken the drug even with a proper warning is a matter to be decided by the trier of fact on all of the relevant evidence...
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> In my opinion, it was open to the trial judge, viewing the evidence as he did, to credit the plaintiff's testimony that she would not have taken the pill had she been told of the danger of stroke, and to determine the causation issue accordingly. Whether a so-called reasonable woman in the plaintiff's position would have done likewise is beside the point. The selection of a method of preventing unwanted pregnancy in the case of a healthy woman is a matter, not of medical treatment, but of personal choice; and it is not unreasonable that notice of a serious potential hazard to users of oral contraceptives could influence her selection of another method of birth control. So long as the Court is satisfied that the plaintiff herself would not have used the drug if properly informed of the risks, this causation issue should be concluded in her favour regardless of what other women might have done.[710]

These lines confirm that the court determined causation-in-fact by using the simple "but-for" test, inquiring as to whether the plaintiff's damage would not have occurred but for the defendant's negligence in failing to issue a proper warning. They confirm the view that, according to the court's finding in general, a subjective standard is to be used in product liability cases as a common law principle, regardless of any specific circumstances. This means, *e.g.*, simply disregard the fact that the products dealt with in these cases are pharmaceuticals, embracing a relatively large variety of distinguishable

products, from over-the counter-drugs to prescription drugs. It also ignores particular problems that follow out of the three-party situation, which might be elsewhere of juridical interest.

The often heard argument[711] that the imposition of a subjective standard would place an undue burden on drug manufacturers was rejected by Robins, J.A. for the following reason:

> The suggestion that the determination of this causation issue other than by way of an objective test would place an undue burden on drug manufacturers is answered by noting that drug manufacturers are in a position to escape all liability by the simple expedient of providing a clear and forthright warning of the dangers inherent in the use of their products of which they know or ought to know. In my opinion it is sound in principle and in policy to adopt an approach which facilitates meaningful consumer choice and promotes marketplace honesty by encouraging full disclosure. This is preferable to invoking evidentiary burdens that serve to exonerate negligent manufacturers as well as manufacturers who would rather risk liability than provide information which might prejudicially affect their volume of sales.[712]

The question is whether this distinction made by the Ontario Supreme Court, also referred to by the Supreme Court of Canada in *Hollis*, is defensible in so far as it makes a distinction between the applicable standards of causation in the different relationships?

In reaching the conclusion that instead of the objective (*Reibl*-) test a subjective test should be applied to product liability cases, Robins, J.A. focused his reasoning on the justification for using a different test for determining causation in doctor-patient informed consent cases, in contrast to manufacturer-consumer failure to warn cases.

> The considerations applicable and the responsibilities involved in a doctor-patient relationship differ markedly from those of a manufacturer-consumer relationship. As between doctor and patient, there is a direct and intimate relationship in which the relative advantages and disadvantages of a proposed medical treatment, including

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[710] *Buchan* at 34 f.
[711] *Buchan* at 35.
[712] *Buchan* at 35.

> the taking of a drug, can be considered, discussed and evaluated. As between drug manufacturer and consumer, the manufacturer is a distant commercial entity, that like manufacturers of other products, promotes its products directly or indirectly to gain consumer sales, sometimes, as in this case, accentuating value while under-emphasizing risks. Manufacturers hold an enormous informational advantage over consumers and, indeed, over most physicians. The information they provide often establishes the boundaries within which a physician determines the risks of possible harm and the benefits to be gained by a patient's use of a drug. Manufacturers, unlike doctors, are not called upon to tailor their warnings to the needs and abilities of the individual patient; and, unlike doctors, they are not required to make the type of judgment call that becomes subject to scrutiny in informed consent actions.[713]

This contextual analysis illustrates the inappropriateness of the doctor-patient test of causation to the manufacturer-consumer relationship.[714] The manufacturer gives a warning to everyone, because he has to address the package insert to every potential consumer who might buy the product. In contrast to that, the doctor advises the patient to take a drug with regard to his diagnosis of this particular patient's special needs.

This allows the final assessment, that generally the simple "but-for" test is to be used in pharmaceutical product liability cases.

b. Special Situation in cases where the "learned intermediary" rule is applicable; manufacturer-"patient" relationship

The causation issue, and the determination of the appropriate test, leads to special problems in cases where the "learned intermediary" rule has been held applicable, when the manufacturer-defendant's breach of the duty to warn has been discussed.

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[713] *Buchan* at 34.
[714] Peppin, at 509.

The first problem has already been mentioned. It lies in the simple fact that a physician is involved in both, in "informed consent" cases as well as in all pharmaceutical product liability cases that do not deal with over-the-counter drugs. The plaintiff is a patient in both cases. The question here is whether it is juridically correct to distinguish between doctor-patient and manufacturer-"patient" relationships for the standard of causation.

One could argue that the same test has to be applied because of an apparent anomaly that otherwise results in cases where a doctor is also alleged to have been negligent.[715] In such instances the doctor might have breached his duty to warn independently of any failure on the part of the manufacturer. If there were different tests applicable in the two kinds of actions, there would be different tests used for answering the same causation issue in the same case, depending on whether the defendant was the manufacturer or the plaintiff's physician.

> Such an argument fails to notice that the causation issue is not quite the same, because in the action against the physician the question would be "what would the plaintiff have done if properly warned by his physician". Against the manufacturer the question should rather be focused on the failure to warn by the manufacturer. As shown before, it is proper to distinguish between these two cases in regard to the different responsibilities, interests involved and other circumstances on the part of the physician in contrast to that of the manufacturer.[716]

The second problem refers directly to the legal construction of the "learned intermediary" rule. This involves the consideration of two issues:

First, is it juridically correct to distinguish between doctor-patient and manufacturer-"patient" relationships for assessing causation from the plaintiff's perspective by using different causation standards when the "learned intermediary" rule is applied? Secondly,

how does the "learned intermediary" affect the plaintiff's burden of proof for the causal connection between the manufacturer's failure to warn and his injury? .

aa. The distinction drawn by two different tests

The problem that arises out of the first issue is: how to justify the apparently unusual result of using different standards of causation depending on whether the lawsuit is focused on the manufacturer or on the "learned intermediary", respectively when both are sued in one action. After all, both defendants were originally part of a single, complex, three-party legal construction, in which the "learned intermediary" rule places the physician between the manufacturer and the plaintiff in the manufacturer's duty to warn sequence.

In his dissenting judgment in *Hollis*, Sopinka, J. elaborated upon these circumstances as follows:

> Moreover, I see no reason why the test for determining the same issue should be different for the physician and the manufacturer. With respect to both, the question for the plaintiff is the same. How would the plaintiff have responded if properly warned by the physician? Is the trial judge to apply two different tests to determine the same question? If so, this could conceivably result in a finding that, vis-à-vis the physician, the patient would have consented, and vis-à-vis the manufacturer, she would not....
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> I fail to understand how a different test for the physician and the manufacturer, which, my colleague acknowledges, seems anomalous, can be redeemed on the basis that a stricter standard can be expected of the manufacturer. This ignores the fact [that] we are dealing with a situation in which the manufacturer's duty to the plaintiff is discharged by informing the physician of risks. The physician is expected to pass this onto the patient. If the risk is one about which the plaintiff ought to be warned, it can hardly be suggested that the physician can water down the warning because a lower standard applies to the physician. One could, perhaps, talk about a

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[715] La Forest, J. in: *Hollis* at 35, for a consideration of this counter-argument.
[716] *Ibid.*

> different standard[s] when comparing the respective duties to warn when the learned intermediary rule does not apply and both the physician and manufacturer have a duty to warn the plaintiff directly. However when the duties of the manufacturer and the physician to warn the plaintiff are to be discharged by virtue of the information received from the manufacturer being passed on to the plaintiff and both the physician and the manufacturer are sued in one action for breach of that duty, there is no room for the application of a different standard. Indeed, the issue of causation has nothing to do with the standard of disclosure. In resolving this issue, the court attempts to determine what the plaintiff's response would have been on the assumption that the appropriate warning has been given in accordance with the appropriate standard. The debate concerns the bases on which that response should be measured, not about the standard of disclosure.[717]

With respect, these reflections cannot be supported. In terms of showing the causal connection between the defendant's failure to warn and the plaintiff's injury, the question to be answered is not quite the same for both possible defendants. In the action focused on the manufacturer's failure to warn, the question for the plaintiff is by no means "how he would have responded if properly warned by the physician", even though the "learned intermediary" rule was found to be applicable under the particular circumstances of the case, and even though the manufacturer's duty to the plaintiff could have been discharged by informing his physician of the risks. It is false because the manufacturer's duty to warn is still owed to the plaintiff, *i.e.*, the duty itself is not off-loaded or transferred to the physician and the duty remains *inter partes*. This means that, if the plaintiff claims the manufacturer's negligence, it has to be his potential warning that must be looked at for the question of causation, not the physician's.

Secondly, when the court concludes that the manufacturer has breached his duty to warn the plaintiff, it means that he has failed to warn directly as well as indirectly. This means that he has not discharged his duty to the plaintiff by warning his physician. The legal

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[717] *Hollis* at 46.

consequence of this situation can only be interpreted so that the "learned intermediary" drops out of the causal sequence, once the manufacturer has breached his indirect duty.[718] Therefore the role of the physician can no longer be taken into consideration in the plaintiff's lawsuit against the manufacturer. The main focus is the manufacturer's negligent conduct. Therefore the issue of causation has to be solved by concentrating on him from the plaintiff's perspective, because all the juridical issues have to be observed within the manufacturer-consumer[719] relationship. Strictly speaking, this interpretation even destroys concerns referring to the use of different causation standards for the manufacturer and the physician. On a proper analysis this problem does not really exist as an integrated complex of issues, and in strict logic is not of legal interest, because both relationships, manufacturer-consumer and doctor-patient, can be assessed absolutely separately as generating entirely discrete issues.

Finally, and this must be made clear, the discussion related to the justification of applying different standards for showing causation has unavoidably involved a consideration of the different disclosure standards of manufacturers and doctors, in terms of finding the right arguments in favour of the distinction. This does not mean that the issue of causation has accidentally got mixed together with the standard of disclosure.

Corresponding with Sopinka, J.'s statement, it can be said that it is the court's responsibility to attempt to determine what the plaintiff's response would have been, on the assumption that the appropriate warning had been given in accordance with the

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[718] Peppin, at 509.

[719] As the physician is legally not part of the original three-party construction any more, the plaintiff in this situation can no longer even be looked at as a "patient", as he is clearly a consumer only.

appropriate standard. By using a subjective test in relation to the manufacturer this task is satisfactorily accomplished for the reasons argued above.

From the opposite perspective, the conclusion must be drawn that the manufacturer's option to discharge his duty to warn, an obligation which he owes in general directly to the consumer, by warning indirectly through the physician, cannot in the last analysis influence the choice of the appropriate test used in product liability cases (which as earlier discussed, is the subjective test). The circumstance that the physician has been put in, between the manufacturer and the consumer, making the consumer a "patient" at the same time, does not mean in terms of legal analysis that the plaintiff's relationship to the manufacturer is exactly equivalent to the one with his physician. The opposite is the case. The doctor-patient relationship is different from the manufacturer-(physician)-"patient" relationship. The plaintiff still is a consumer from the manufacturer's perspective and has to be treated as such with all the legal consequences which ensue. Notable among these is that there is no reason for modifying the commonly used test in product liability cases or other tortious actions, as there was (for well known reasons already discussed) in the special situation between the doctor and the patient.

bb. Effect or influence of the "learned intermediary" on the evidentiary burden of proof

Another issue that courts reflect on in cases of this nature, regarding causation, has been the role of the physician in the causal sequence shown by the plaintiff. This will be based on the assertion, put forward by the defendant, that the learned intermediary would not have passed on the warning about the risks of consuming the product to the patient. This

defence typically arises after the manufacturer has been held responsible for breaching his duty to warn, by failing to issue a sufficient warning either directly to the consumer or indirectly through the consumer's physician, whereupon the defendant argues that there was no direct link between his breach of the duty to warn and the patient's injury. He usually alleges that the learned intermediary would not have advised the patient appropriately, even if a warning had been issued to him. Consequently it would have made no difference as to whether or not he would have provided the physician with a warning. In other words a warning would have had no effect on the information actually received by the plaintiff, as a result of the physician's disclosure practice. This defence poses the question of "proximate" or "intervening" causation, as it is aimed at convincing the court that it was actually not the manufacturer's failure that caused the injury suffered by the plaintiff, so disrupting the plaintiff's arguments regarding causation-in-fact.

Thus, the courts have acknowledged that an intervening cause of this kind might exonerate the manufacturer from liability where the learned intermediary's intervention superseded any possible default arising from the manufacturer's failure and therefore occasionally might establish absence of his negligence-liability.[720]

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[720] Supreme Court in: *Hollis* at 42; Ontario Court of Appeal in: *Buchan* at 30:

> While the distribution of the Rx Bulletin did not relieve Ortho of its duty to warn the medical profession, I do not take issue with the submission that the conduct of a prescribing doctor may exonerate the manufacturer from liability where the evidence establishes that, as a result of what the doctor knew, adequate warnings would have had no effect on whether or not he would have prescribed the drug. The question is whether that conclusion can properly be drawn from this case.

This corresponds to the judgment in the German *"Impletol"*case[721], where causation could not be established after the plaintiff's physician had admitted in his testimony that he usually did not pay attention to package inserts and would have not read a warning anyway. The German Federal Supreme Court has also addressed this same causation issue. The *"Estil"* decision[722], concerned the question whether and to what extent a third person's conduct - here the physician's intentional misapplication of pharmaceutical products - might interrupt the imputation of liability to the manufacturer for the damaging result. The Court denied that any such disruption into the causal sequence shown by the plaintiff, (*i.e.*, that the warning's insufficiency caused the damaging mis-performance of the injection by the physician) had occurred. Nor, accordingly, was the manufacturer exonerated. Furthermore, the defendant had not supplied enough evidence of such likely aberrant conduct on the physician's part, as would rebut the presumptive causal connection shown by the plaintiff. In other words: the defendant had not adduced persuasive evidence that the damage would have occurred anyway even if he had not broken his duty.

At the same time the Canadian courts have seen themselves confronted with another problem, which again arises out of the defendant's contention, but has to be legally distinguished from the intervening cause defence in general. The question relates to the apportionment of the burden of proof between the litigation parties and is: whether the plaintiff is required to show that the learned intermediary would have passed the warning

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[721] *OLG* Stuttgart [1990] VersR 631 at 633.
[722] *BGH* [1972] NJW 2217 at 2221.

on, as an element of causation, to satisfy the causation test and so succeed in his claim against the manufacturer?

The German courts have been confronted with the same question and have come to the conclusion that the plaintiff in the first instance generally does not have this onus of proof, unless the defendant is able to rebut the plaintiff's *prima-facie* evidence on this matter, providing evidence that would show another possible causal sequence based on reasonable grounds. As we shall presently see the Canadian courts have belatedly arrived at the same conclusion, which German experience has shown to provide for quite reasonable and satisfactory judgments in consumer-manufacturer litigation.

(1). The Supreme Court's solution in *Hollis*

La Forest, J. countered this defence argument in *Hollis* while considering the physician's warning practices with the following reasoning:

> I do not propose to enter further into or assess these factors. I say this because, while Dow is correct in submitting that there was some ambiguity at trial concerning Dr. Birch's warning practices in 1983, Dow's argument is based upon the assumption that to succeed in her claim against Dow Ms. Hollis must prove that Dr. Birch would have warned her if Dow had properly warned Dr. Birch. I do not think this assumption is well founded. Ms. Hollis, it will be remembered, demonstrated that Dow had breached its duty to warn her of the risk of rupture, that she would not have undergone the medical procedure if she had been fully informed of the risks, and that she suffered injury from the rupture. Had Dr. Birch been adequately warned but had not passed on the information to Ms. Hollis, Dow would, it is true, have been absolved of liability by virtue of the learned intermediary doctrine. But I fail to see how one can reason from that, for Dow to be liable, Ms. Hollis must now establish that Dr. Birch would have informed her if he had known. To require her to do so would be to ask her to prove a hypothetical situation relating to her doctor's conduct, one, moreover, brought about by Dow's failure to perform its duty. While the legal and persuasive onus in a negligence case generally falls on the plaintiff, I

> do not see how this can require the plaintiff to prove a hypothetical situation of this kind.[723] (emphasis added)

This paragraph basically confirms everything that was developed in the legal analysis above; namely, that the plaintiff has to prove causation using the "but-for" test addressed through subjective criteria, to indicate that if properly informed he would have refused to take the manufacturer's product, which would have then avoided the injury. In order to satisfy the subjective test of causation, the plaintiff does not have to prove that the learned intermediary would not have ignored the manufacturer's warning.

Excursus: Other issues discussed in *Hollis* - The use or misuse of analogy:

At this point I would like to pause and stress that I cannot see apparent similarities to the special causation problems in other well known problematic causation cases.

The Supreme Court of Canada considered the reasoning in *Lewis v. Cook*,[724] as helpful in this context. This also became a main focus in Sopinka, J.'s dissenting judgment.

The leitmotiv underlying this reflection upon other problematic causation cases is obviously the existence of behaviour on the part of the defendant that leads to situations presenting "apparently" insoluble difficulties of proof. This made the Court draw an analogy to those cases where the ordinary burden which rests on the plaintiff to prove causation has been either reversed, *i.e.*, shifted to the defendant, or relaxed. The question is whether the principles developed in these cases need to be considered or applied in the

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[723] *Hollis* at 40.
[724] [1951] S.C.R. 830, [1952] 1 D.L.R. 1.

present scenario. I would suggest not, because the situation here is distinct upon any reasonably viable analysis, and can be solved with ordinary causation principles, as will be shown below. The only problem that might be looked at more closely is the problem of "intervening causation".

In *Cook v. Lewis* the plaintiff's problem was to prove the sole responsibility of one defendant, as he was only injured by one bullet while both defendants appeared to have shot at him. The plaintiff's dilemma was, that he had to deal with the "hypothetical" situation, that there were two equally possible negligent defendants to his claim for compensation, which was a situation created by the defendants. This case is, in truth, so distant in substance from our present situation as to afford no useful comparison. The present issue concerns the sole responsibility of the pharmaceutical manufacturer for his failure to warn; a responsibility, which, at this stage, exists quite independently and apart from that of the physician. I think that the *Cook* quotation chosen by La Forest, J. gives too much verisimilitude to the manufacturer's contention, that the plaintiff is called upon to prove what a doctor would have done in a hypothetical situation. This "hypothetical" situation appears to be somewhat distinct from the one looked at in *Cook*. It is rather the manufacturer's assertion that builds an artificial conflict for defence reasons, which on close examination is not really good enough to actually challenge the causal connection shown by the plaintiff, or to establish a dilemma such as that created in *Cook*. Here it is by no means equally impossible for the plaintiff to prove that the damage was a result of the manufacturer's act.

Nor does this case really lead to a causation dilemma like that in *Cook*. Therefore it should not have been given such prominence. Nor should such stress have been laid on the necessity of reviewing all these different devices for solving causation problems. Simply put the rationale of this case and of those discussed by the Court in debating its applicability[725] is remote from the issues relevantly presented by the type of cases at issue.

(2). The Ontario Court of Appeal's approach

A somewhat similar observation, regarding the same "apparent" causation problem in cases of this nature, was made by the Ontario Supreme Court in *Buchan*. There the defendant alleged that the manufacturer's deficient warnings could not be said to have proximately caused the plaintiff's injury, considering the physician's independently acquired state of knowledge received from other sources, in this instance a medical bulletin. The defence argument was that in light of that knowledge there was no need for the manufacturer to warn the physician, because a warning would only be required where the situation called for it. In other words, no one needs notice of what he already knows. Before the court examined whether this conclusion could properly be drawn from the evidence in this case, it made clear that the hypothetical question of the physician's possible conduct is not part of the plaintiff's elementary onus of proof.

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[725] Notably *Snell v. Farrell*, [1990] 2 S.C.R. 311; *Mc Ghee v. National Coal Board* [1973] 1 W.L.R. 1 (H.L.); *Wilsher v. Essex Area Health Authority*, [1988] A.C. 1074 (H.L.), all discussed in Sopinka, J.'s dissenting judgment in *Hollis*.

> Once the breach of the duty to warn the prescribing physician has been established, I think it is fair and reasonable to presume that the inadequacy of the warning was a contributing cause of the ingestion of the drug. It ought not to be incumbent on a plaintiff to prove as part of her case what her doctor might or might not have done had he been adequately warned. One can assume that a doctor would not ignore a proper warning or fail to disclose a material risk of o[r] otherwise act negligently. Even if the evidence were to indicate that the doctor was negligent, the manufacturer would not be shielded from liability if such negligence were a foreseeable consequence of the breach of duty to warn. The presumption may, of cause, be rebutted if the defendant comes forth with evidence that despite the inadequacy of the warning, the doctor's conduct toward his patient would have been the same whether or not the manufacturer was in breach of the duty.[726]

In correspondence with the Supreme Court, the Ontario Court of Appeal is of the view that, in establishing the liability of the manufacturer, the law does not require the plaintiff to prove what the doctor might have done as an element of his case in order to satisfy the subjective test of causation.[727] Whether one comes to this conclusion, like Robins, J.A. by speaking of a presumption arising on proof of the breach of the duty to warn, or by calling it something else, there is agreement on this matter insofar as there is no call to put an onus of proof like this onto the patient.[728]

(3). Sopinka J.'s dissenting opinion

Contrary to these findings, Sopinka, J.[729] is of the view, that the plaintiff must show as a further part of his claim that his doctor would have warned of any dangers that had been brought to his attention. In accord with the present analysis, he carefully distinguishes in

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[726] *Buchan* at 30. This was almost identically stated in the German *"Estil"* decision concerning the accidentally mis-performed injection of the physician, which was obviously foreseeable and could have easily been anticipated by the product's manufacturer, *BGH* [1972] NJW 2217 at 2221.
[727] Also Peppin, at 513.
[728] Sopinka, J. in: *Hollis* at 47 f.
[729] *Ibid.*

his statement between the onus of proof that rests on the plaintiff to establish causation-in-fact as part of his claim and the question of possible evidence that might interfere with the causal connection shown by the plaintiff. But he proceeds on the assumption that the plaintiff has not met the requirements of his ordinary burden of showing causation, until he manages to show, as a further element of causation, that his doctor would not have ignored the manufacturer's information. This is expressed by his statement, that

> ...if Dr. Birch would not have passed on information from Dow to Ms. Hollis, Dow's failure to provide the warning cannot be said to have contributed to Ms. Hollis' injury. Liability cannot be based on failure to take measures which would have no effect and be pointless.[730].

He also qualifies this situation as *"absence of cause"*.[731] This conception does not do justice to the circumstance, that the plaintiff in these cases has in fact revealed the defendant's failure and shown a connection to the injury. Whether the court has to question this causal connection shown by the plaintiff, after sufficient evidence is adduced by the defendant which might lead to the conclusion that the manufacturer's failure was not the cause for the injury, is a different issue. Following this route, La Forest, J. inferred that the plaintiff had shown all the elements of her case, and after considering the evidence concerning the manufacturer's warning practice, he decided not to enter further into or assess these factors,[732] obviously because in his view there was not sufficient evidence adduced by the defendant even to raise the issue of causation. This does not mean that the court is *"treating causation as irrelevant"*[733] as Sopinka, J.

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[730] *Hollis* at 48.
[731] *Ibid.*
[732] *Hollis* at 40.
[733] *Hollis* at 48.

criticises. It is just a matter of how the court dealt with the whole problem. In opposition to that, Sopinka, J. is obviously of the opinion that only if the burden of proof had been shifted to the defendant could the plaintiff be partially relieved of his burden of proving causation.

It is not quite clear why he proceeds like this; whether it was because La Forest, J. had drawn a close analogy to the case of *Lewis v. Cook*, a comparison which admittedly gives rise to criticism; or whether he felt obliged to do so, because he wanted to take into account the circumstance that the "learned intermediary" rule was found to be applicable in the present case. As a result he might have assumed that the burden of proof implies requiring the plaintiff to show that her injuries would not have occurred, had the manufacturer discharged its duty to warn the prescribing physician of any dangers inherent in the product[734]. This assumption fails to take into account that the essential reproach levelled against the defendant is that he has not warned at all, not only that he has not warned the physician. It has to be kept in mind, that the manufacturer's duty to warn is, with or without the "learned intermediary" rule, still owed to the consumer. Hence, the plaintiff's burden of proving his case has been discharged, when he demonstrates that (1) the manufacturer has breached his duty to warn and (2) that this conduct has somehow materially contributed to the injury. This is because, besides his failure to warn the physician, there is still another part of the manufacturer's failure left, namely to provide the patient with a warning directly or at least "by one means or

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[734] *Hollis* at 47.

another". To warn the physician was not the manufacturer's one and only duty and at least not his original duty, as owed to the consumer. These factors cannot be treated as irrelevant by making allowance for the circumstance, that the manufacturer could have discharged this duty if he had warned the physician; or in other words that, had the physician been adequately warned, the manufacturer would, it is true, have been absolved of liability by virtue of the learned intermediary rule, whether or not the physician chose to pass that information on to the patient. However, this is not the situation we are examining here. At least it can be said, that the manufacturer's negligent conduct materially contributed to the result where the injury is the consequence of the lack of information. Even with the "learned intermediary" rule the duty to warn is always owed to the injured product consumer. Therefore the circumstances in the present case by no means provide an absence-of-cause situation.

The causation conflict that arises out of the possibility that the plaintiff's physician might have failed to pass on any warning does not automatically eliminate the causal connection shown by the plaintiff, when the physician was not in fact even warned. It might raise a question of an intervening causation in the case against the manufacturer but only in terms of a defence assertion, which has to be proved by the defendant-manufacturer. Otherwise it would put too much emphasis on a hypothetical sequence of causation, which was not even put into motion because of the defendant's failure to perform the duty. This means that , when the defendant did not even meet the requirements on his part, namely one of the possible warning options, the plaintiff cannot be requested to

show more than he would normally need to, when only he and the manufacturer were involved. Figuratively the physician was not involved in this causal sequence.

As the conduct of the physician is presently not an element of causation to be put in evidence by the plaintiff, the plaintiff need not prove a hypothetical situation. Consequently there is no need to review the entire constellation of cases that either reversed or relaxed the ordinary burden which rests on the plaintiff to prove causation and we need not enter into further details of these cases.[735]

Further grounds for disputation, however, are furnished by the way in which Sopinka, J. processes the approach of the Court of Appeal in this matter.[736] It has to be pointed out that this was not an alternative method of obviating the plaintiff's burden of proof, but rather a comprehensible suggestion of the court as to how to deal with the issues in question. The "rebuttable presumption" expressed by the court did not mean to relieve the plaintiff from establishing all the generally required elements of causation, as this was not in fact the issue in the present cases, as repeatedly shown above. The intention, moreover, was to establish a judicially fair and satisfying solution for the issue in question, namely the joint operation of the plaintiff's obligation to prove causation, as part of his claim against the manufacturer, and the effect of the "learned intermediary" rule on this onus of proof. The court came to the result, as correctly recognised by Sopinka, J.,[737] that the plaintiff need not prove that her doctor would have warned her of any dangers, unless the defendant presents some evidence tending to show that the doctor might not have in fact

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[735] For further details see *Hollis* at 48-51.
[736] *Hollis* at 50 f.

passed along the appropriate warning. It is incumbent on the defendant to adduce sufficient evidence to raise the issue of causation, the so-called evidentiary burden of proof. This observation however was found by applying ordinary principles of causation.[738]

(4). Additional explanations

The following explanations[739] will be added in support of La Forest, J.'s judgment. The arguments support the conclusion that the physician's hypothetical conduct does not require the plaintiff to prove what the physician might have done, because it is up to the defendant to show a disrupted causal sequence or causal intervention in these cases.

(a).The negative side, deficit, restricted or limited effect of the learned intermediary rule

Having failed to warn even the learned intermediary, the manufacturer has entirely failed in its duty to warn the plaintiff who has ultimately suffered injury by using the product. This is enough to require the plaintiff to show, including the required causal connection, because it provides a full picture of the manufacturer's liability. On first impression, there

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[737] *Hollis* at 50.

[738] In this context - and this is just about as close as it gets - one may refer to the judgment in *Snell v. Farell* at 326 f., where the court decided not to reverse the burden of proof, but to stay with the ordinary principles of causation:

> If I were convinced that defendants who have a substantial connection to the injury were escaping liability because plaintiffs cannot prove causation under currently applied principles, I would not hesitate to adopt one of these alternatives. In my opinion, however, properly applied, the principles relating to causation are adequate to the task.

[739] The arguments arose in response to Sopinka, J.'s dissenting judgment in *Hollis* at 47 ff. and basically provided counter-arguments.

is no element missing that would suggest a need to explain what the physician might have done in the hypothetical situation which might have arisen, had the manufacturer fulfilled its duties, a situation that has never occurred. Whether the physician's "failure" to disclose the received information to his patient acts as a break in the causal chain, shown by the plaintiff in his claim against the manufacturer, concerns the defence arguments. It should be on the defendant to prove such an allegation, because it encompasses a different course of causation to the case that might destroy the plaintiff's demonstration of causal connection.

Where the manufacturer did not even warn the physician, thus discharging him according to the learned intermediary rule, he cannot put the injured consumer into a position where it is now on the latter to address the argument that a warning to the learned intermediary - which does not even exist in this case - would have avoided his injury, if it had been passed on to him. This would demand more from the plaintiff then he would have to show without the learned intermediary rule. Therefore this issue should not be a matter for the patient to prove in order to satisfy the requirements of the (subjective) "but-for" test of causation in his claim.

It is in fact the defendant's negligent conduct that has formed the grounds for the uncertain procedural proof situation based on hypothetical circumstances. The dilemma that nobody knows if the physician would have passed the warning on to the patient, in other words that this defence is based on a hypothetical possibility or probability, is

rooted in the failure of the defendant. If he had met the requirements of his duty, the situation would be actual, capable of demonstration by evidence, and not hypothetical.
It is not plausible to argue that despite the manufacturer's failure to warn, the hypothetical possibility "what if the doctor would have not passed the (not-) warning on?" should play a role in the question of causation.

This cannot be right and would, dissecting the problem even more, only tend to show that the indirect warning given to the doctor was not enough sufficiently to inform the patient, which is the main concern in these "duty to warn" cases.
The circumstances moreover reveal that the learned intermediary rule contains a deficiency. Proceeding on the assumption that the manufacturer[740] would actually be able to show enough evidence to convince the court that, providing the learned intermediary with information - which is meant to be for the consumer - would have been useless as he would have not passed on a warning that was given to him, this would only provoke a reopening of discussion about indirect warnings. In this case the indirect warning given to the physician was obviously not sufficient to discharge the duty owed to the "patient". It would have to be concluded that an additional warning directly issued to the "patient" would be required to fulfill the duty to warn.[741]

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[740] I formulate the assumption in this way because if at all it has to be the manufacturer who has to adduce sufficient evidence to even raise the issue of causation, as it is presently in question.
[741] I intend to point out the unsatisfactory result, referring to La Forest, J.'s finding in *Hollis* at 40, that "Dow would, it is true, have been absolved of liability by virtue of the "learned intermediary" doctrine", had he adequately warned Dr. Birch, even though he then, on his part, had not passed on the received information to Ms. Hollis.

The "learned intermediary" rule is supposed to relax or lighten the manufacturer's warning obligation where it makes sense and is justifiable. *I.e.*, where it can be said that the manufacturer, even though he has not warned the "patient" directly, has addressed a warning to the learned intermediary and this can be acknowledged as comprehensible insofar as it can be assumed that a physician would transmit the necessary information or otherwise use it to protect the patient from harm.

This is not the case where the manufacturer has not met these requirements because he has not given adequate warning to either of these parties. Where a warning is missing altogether, the learned intermediary rule should no longer be open to discussion in terms of questioning the duty breaker's liability, whether in relation to the causation issue or to anything else, and should certainly not affect the plaintiff's ordinary burden of proof.

One might reasonably suppose that, once the learned intermediary rule was found applicable to the case, for the sake of legal consistency in judging the case at hand, its influences on other legal issues (such as the burden of proof regarding causation) that might occur throughout the case and that have to be dealt with to do justice in the particular case, could not be neglected. This would be true even though they might pose an additional burden on the plaintiff (such as here: showing that the learned intermediary would have passed a potential warning on, which would generally not be part of the plaintiff's claim against the manufacturer in the absence of the "learned intermediary" rule). This line of argumentation, however, would probably only apply where it could be considered reasonable to do so; but not in situations, where the manufacturer did not even take advantage of the alternative method of discharging the obligation provided by the "learned intermediary" rule. This means that there must be grounds for contemplation on

this issue in view of the legal consistency regarding the final judgment, namely the influence of the "learned intermediary" rule on the procedural position of the plaintiff in proving causation. In cases where the legal effect of this rule did not even come into play, this issue might be rather left out of the further legal assessment of the case, particularly if it puts an additional burden on the injured plaintiff.

To make it clear, the only role the learned intermediary can possibly serve is that, in certain circumstances, an indirect warning addressed to the physician can be considered as being sufficient. Other than that, *e.g.*, in cases where the manufacturer did not warn at all, there is no room for any further discussion about or even consideration of the "learned intermediary" rule, whether in relation to causation issues or anything else.

As a result, that opinion cannot be sustained, which holds that the hypothetical possibility of the doctor's intervention automatically challenges the causal connection between the manufacturer's breach of the duty and the patient's injury, or even requires the courts to raise the issue of causation. There is no room for any doubt, until the defendant shows and proves the opposite, or for example that it was not his failure that caused the patient's loss, regardless of whether or not the consumer was provided with the necessary information directly or indirectly. Therefore, the latitude or scope for legal argument established by the application of the learned intermediary rule should definitely end when the manufacturer has not given a warning at all. This means the application of the rule to the case cannot unreflectively be used as a defence in favour of the manufacturer, in terms of causation issues, when he has breached his duty in every respect. In that case the "learned intermediary" rule would not even be allowed its legal effect.

(b). The legal goal is consumer protection

The learned intermediary rule has to be looked at and in its effect considered with regard to the main issue of providing the consumer, and not the manufacturer, with a higher protection[742].

The learned intermediary rule is only meant to serve as a procedural alleviation for the manufacturer, with regard to his warning obligation in a lawsuit advanced against him. The rule has been held to be applicable only in exceptional circumstances and is only legally justified as such. The primary aim to be achieved has always been to establish the highest possible protection for consumers against risks presented by manufacturer's products that cannot be produced with total user safety when they have been put on the market. Therefore the product needs to be supplied with adequate package information addressed to the ultimate consumer. It would seem that we are at least entitled to question whether the consequence of the application of the learned intermediary rule on the other hand can possibly lead to a procedural disadvantage to the plaintiff-consumer, on the causation issue. It seems especially questionable, if the rule stating a legal exception in certain circumstances in favour of the defendant (but still requiring a ground of justification vis-à-vis the plaintiff) can legitimately be so far reaching. By the same token it has to be supposed that the exceptional legal consequence of the rule cannot put the plaintiff in a worse situation than he would have been in without the rule. Looking to the

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[742] Peppin, at 516:

procedural situation, the patient would have to sue the physician who did not pass the information on to him, if the learned intermediary rule allows the manufacturer to escape liability by warning only the physician. Because it is the manufacturer who created the situation where not even the physician was informed, it has moreover to be taken into account that this also makes such legal proceedings more difficult for the plaintiff. His chances of winning a case against his physician are largely dependent on the information the physician actually got, which he could have passed on. As long as he does not get additional information himself, he cannot give more than what he has, to meet his own obligations.

This concern is illustrated in La Forest J.'s further analysis[743] of the issue in *Hollis*, which includes additional reasons that legally justify the conclusion he reached.

> Simply put, I do not think a manufacturer should be able to escape liability for failing to give a warning it was under a duty to give, by simply presenting evidence tending to establish that even if the doctor had been given the warning, he or she would not have passed it on to the patient, let alone putting an onus on the plaintiff to do so. Adopting such a rule would, in some cases, run the risk of leaving the plaintiff with no compensation for her injuries. She would not be able to recover against a doctor who had not been negligent with respect to the information that he or she **did** have; yet she also would not be able recover against a manufacturer who, despite having failed in its duty to warn, could escape liability on the basis that, had the doctor been appropriately warned, he or she still would not have passed the information on to the plaintiff. Our tort law should not be held to contemplate such an anomalous result.[744] (emphasis in original)

Causation analysis needs to carried out with creativity, bearing in mind the power dynamics, in order to serve the underlying purposes of harm prevention and patient control of decision-making.

[743] Here, La Forest, J. also refers to the quotation of Robins, J.A. given above.

[744] *Hollis* at 42.

Starting from these deliberations, we have to proceed on the assumption that the rule was not meant to conflict with causation issues. It was established in the frame of the breach of the duty element of negligence. The intention behind this rule was certainly not supposed to create an open door for various defence opportunities, or meant to serve as a procedural handicap for the plaintiff.

This is also expressed in the concluding passage of La Forest J.'s reasoning which provides a summary of the legal rationale that should be applied accordingly when dealing with the plaintiff's claim against the manufacturer:

> The ultimate duty of the manufacturer is to warn the plaintiff adequately. For practical reasons, the law permits it to acquit itself of that duty by warning an informed intermediary. Having failed to warn the intermediary, the manufacturer has failed in its duty to warn the plaintiff who ultimately suffered injury by using the product. The fact that the manufacturer would have been absolved had it followed the route of informing the plaintiff through the learned intermediary should not absolve it of its duty to the plaintiff because of the possibility, even the probability, that the learned intermediary would not have advised her had the manufacturer issued it. The learned intermediary provides a means by which the manufacturer can discharge its duty to give adequate information of the risk to the plaintiff by informing the intermediary, but if it fails to do so it cannot raise as a defence that the intermediary could have ignored this information.[745]

There is something wrong with the material substance of this defence. The learned intermediary rule cannot make it easier for the defendant by providing two possibilities to escape liability: first, on the level where the breach of the duty is under discussion and, in addition after this part of the negligent act has been determined, in relation to the causation issue, even though the rule did not help to decide in favour of the defendant on the first level. This would constitute a double advantage to the defendant, corresponding with a double disadvantage on the plaintiff's side.

This legal assessment holds good even if we admit that under certain circumstances the judgment might reach another result. Thus, *e.g.*, if one would argue that a judicial alleviating device, that is on the one hand established to support the defendant might, as a matter of legal consistency, require on the other hand, that the special legal structure (here: triangular situation between parties involved) has to be considered throughout the whole assessment of the defendant's negligence, even though placing a procedural disadvantage on the plaintiff. However, these circumstances cannot be found in the present situation. Thus, the peculiarity of this situation lies in the circumstance that the manufacturer, as a matter of evidence or of fact, simply failed to fulfill his obligation. Therefore, it does not seem right to bestow a favour on him, by loading onto the injured plaintiff the procedural task of furnishing proof of causation in hypothetical circumstances, a task he would not otherwise have had. After all, without the existence of the rule it would be on the defendant to adduce sufficient evidence, even to raise the causation issue and challenge the causation asserted by the plaintiff, by showing that the consumer, even though properly warned, would have taken the drug, either because he was convinced to do so, despite the warning, or for any other reason, *e.g.*, because his physician would have advised him to do so.

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[745] *Hollis* at 43.

(c). The doctor's obligations towards his patient are basically not part of the patient's law suit against the manufacturer; they exist collaterally and they are of a different quality

The warning obligation in the manufacturer-consumer relationship exists, obviously, between the manufacturer and the consumer. This should basically also be the focus in any issue that arises out of any litigation between them. The kind of duty the doctor owes to the patient is a different field and should not be mixed with the manufacturer's duties. To make it clear, the hypothetical possibility that the physician might not have passed on the warning does not certainly interrupt the causal link between the non-existent warning (manufacturer's failure) and the result (patient's injury). Furthermore, it does not necessarily establish absence of the manufacturer's negligence. Whether the doctor himself has additionally failed in his performance is another question and in the claim against the manufacturer that would be an issue which would have to be proved by the defendant as an interfering or intervening cause.

3. Intervening causation

Under this heading we will look at the consequences in those situations where the defendant has furnished sufficient proof to raise the question of "intervening causation". Once the manufacturing company has been found to have breached its duty of disclosure, causation cannot be found on the basis of the subjective test, where an intervening cause breaks into the causal sequence shown by the plaintiff. This will occur when the evidence, normally adduced by the defendant, shows that the plaintiff would have decided

to take the product independently of a warning issued by the manufacturer, or that the physician as the "learned intermediary" was an independent cause for the patient's injury. As a result the plaintiff can lose on the issue of causation when (a) he already knew of the risks, or (b) if this would be the case on the part of his physician, or (c) if according to his general practice the physician would not have told him about the risks.

Although the presumption set out in *Buchan v. Ortho Pharmaceutical*, that in general the physician would behave non-negligently in disclosing the risks, improves the plaintiff's prospects considerably, it still leaves room for proof of the physician's situational or habitual non-disclosure.[746]

a. The plaintiff's knowledge

A situation is imaginable where, for example, the plaintiff's knowledge about the risks of the product was so complete that it would have made no difference, whether the manufacturer would have warned him or his physician or not, because he was able to make an informed decision about the usage of the product. Consequently the absence of information was not a cause of his consenting to the product's use.

In *Davidson v. Connaught Laboratories*,[747] the plaintiff's knowledge, acquired independently of the defendant doctors and the defendant vaccine manufacturer, meant that the plaintiff would not have acted differently if the defendants had given an adequate warning. In this case a known risk of paralysis and even death, a risk in the 1/5,000 to 1/8,500 range, arose for a vaccinated individual. Davidson had come in contact with a

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[746] Peppin, at 514.

rabid cow before leaving his family farm in Ontario for a trip to British Columbia. Supplied with the vaccine he returned to Ontario, where shortly after the termination of the injections, he declined progressively into a state of paralysis, a condition of polyneuritis caused by the rabies vaccine, manufactured by the defendant company. He had received full and detailed information of the vaccine's risks, including the risk of paralysis, when he spoke with Dr. Kettyls[748], a virologist in British Columbia. The other doctors involved, including the defendant doctors, did not warn him of the risks. Although the written warning on the printed material placed in the boxes of vaccine given to the doctors was found inadequate and unreasonable in the circumstances of the case, seemingly the "but-for" test for this particular plaintiff could not be met because, *inter alia*, of the plaintiff's independently acquired knowledge.

> ...but the defendant manufacturer also escapes liability because full information of the risks was in fact given to the plaintiff in British Columbia. Nothing that they might have put into the brochure or left out of it would have made any difference in this particular case. Everything that the plaintiff could possibly have wanted to know, was communicated to him in great detail by Dr. Kettyls and was understood by him. Despite this data given to him about side-effects, the plaintiff chose to run the risk. Consequently, the lack of information in the pamphlet was not a cause of his injury.[749]

b. The physician's knowledge

The plaintiff may also lose the action against the pharmaceutical company if his physician possessed independently acquired knowledge of the product's risks. In *Buchan*, Robins, J.A. acknowledged that the knowledge of a doctor might exempt a manufacturer from

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[747] (1980), 14 C.C.L.T. 251 at 277 (Ont. H.C.).

[748] Dr. G. Kettyls was a member of the Special Diseases Committee in British Columbia, in charge of releasing the vaccine and therefore involved in this case. He was not sued by the plaintiff, but testified in the trial.

liability.[750] Following this, La Forest, J. in *Hollis*, though putting clearer emphasis on the exceptionality of this situation, makes a similar concession.[751] The situation, however, remains debatable.[752]

Even if pharmaceutical companies may not rely on physicians to perform independent research[753] that might insulate them from liability, such independently acquired information must create an intervening actor at some stage.[754] For instance, in *Davidson v. Connaught Laboratories*, Dr. Kettyls' independently acquired expertise did not alter the company's duty, as this duty is non-delegatable; but it did lead to a finding of no causation in favour of the drug company, since it had been conveyed to the plaintiff.[755]

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[749] *Davidson v. Connaught Laboratories* at 276 f.

[750] *Buchan* at 30:

> I do not take issue with the submission that the conduct of a prescribing doctor may exonerate the manufacturer from liability where the evidence establishes that, as a result of what the doctor knew, adequate warnings would have had no effect on whether or not he would have prescribed the drug.

[751] *Hollis* at 42:

> ... the manufacturer might be able to adduce evidence that the doctor's conduct might have been the same whether or not the manufacturer was in breach of his duty. I should say whatever effect this might have regarding the apportionment of liability between the doctor and the manufacturer in the event that the doctor is also found to be negligent, it in no way absolves the manufacturer from liability to the plaintiff, except in cases where some extraneous conduct by the doctor would have made the failure to give adequate warning irrelevant.

[752] Peppin, at 514.

[753] Linden, J. in: *Davidson v. Connaught Laboratories* at 276:

> A drug company cannot rely upon doctors to read all the scientific literature outlining the specific dangers involved in the many drugs they have to administer each day. They are busy people, administering to the needs of the injured and the sick. They have little time for deep research into the medical literature. They rely on the drug companies to supply them with the necessary data.

[754] Peppin, at 513.

[755] *Davidson v. Connaught Laboratories* at 277. Additionally this relieved the defendant doctors from liability, as the absence of information was not a cause of the plaintiff's consenting to the injections, *Davidson v. Connaught Laboratories* at 271 f.

Although not discussed in these terms, seemingly the physician's independent expertise, communicated to the plaintiff effectively insulated the drug company from liability.[756] A controversial assessment might be made, where the doctor is actually aware of the risks because of his own reading and research in reputable medical journals, but has been given inadequate risk information by the negligent pharmaceutical company, or has been influenced in his opinion as to the drug's safety and the need to inform patients of its risks. In these situations the promotional efforts of the company, the degree of reliance by the doctor on the company, and the nature of the independent source of information are all factors to be taken into account in assessing the impact of the company's non-disclosure on the doctor's behaviour. [757] For instance, in *Buchan* the Ontario Court of Appeal found that Ortho Canada had promoted the drug's safety through sales representatives and counteracting reports to such an extent that the physician could not be categorised as an independent cause.[758] Ortho's barrage of promotional activities even overshadowed the lengthy warnings circulated to the medical community in the Rx

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[756] This conclusion, that the physician's own knowledge forwarded to the patient can be an intervening causation that might exonerate the manufacturer from liability, can be drawn from the context, although in this case it was not the treating defendant physician who fully informed the plaintiff. *Davidson v. Connaught Laboratories* at 277.

[757] Peppin, at 515.

[758] Robins, J.A. stated in: *Buchan* at 31:

> Ortho's failure to give physicians a warning commensurate with its actual knowledge of the dangers inherent in its products combined with the efforts of its sales representatives to minimize those dangers and counteract reports of adverse side-effects plainly influenced the doctor's opinion as to the drug's safety and the need to inform patients of risks. It is therefore not unreasonable to conclude, as I infer the trial judge did, that the doctor's failure to disclose the risk of stroke (or, for that matter, any thromboembolic risk) to the plaintiff was contributed to by the inadequacy of Ortho's warnings, devoid as they were of any reference to stroke, and the promotional tactics of its pharmaceutical salesmen. In these circumstances, I cannot agree that there was no causal link between Ortho's breach of the duty to warn and the plaintiff's ingestion of the drug, and, it follows, the doctor's intervention cannot operate to exonerate Ortho from liability for its breach of duty.

bulletin[759]. Consequently liability may be imposed to the extent that the doctor is dependent on or lulled by the promotion of the company. Similarly, the heavier the barrage of promotional materials the more foreseeable is the doctor's failure to disclose. In most cases the volume of marketing would swamp the trickle of risk information.[760] Under these circumstances the physician's intervention cannot be said to operate to exonerate the pharmaceutical company from liability for its breach of duty. The learned intermediary does not act independently according to his own opinion in such a manner, so as to break into the causal sequence. He is rather acting in dependence on the information issued to him by the company, effectively dropping out of the causal chain between the manufacturer company and the patient.[761]

c. The physician's warning practice

A plaintiff may also lose his action against the drug company where sufficient evidence can be adduced that his physician makes a practice of not disclosing risks. In the ideal case of indirect warning, the drug company has to supply the physician with the necessary data about the product's use, while the physician is expected to make the individual decision about what treatment to advise for each patient, based on the right balance between the patient's best interests and the information received. However, the physician's warning practice was obviously one of the causal grounds on which the case

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[759] A 44-page report prepared by special advisory committee to the Food and Drug Directorate which contained essentially all the available information, which the Minister of Health had directed to be sent to each physician.
[760] Peppin, at 513.
[761] Peppin, at 511.

against the pharmaceutical company failed in *Davidson v. Connaught Laboratories*[762]. In this case the court found that even full information that had been included in the sheet inserted in the vaccine boxes would not have made any difference to the two defendant doctors. The court found that the evidence was clear that it was not their practice to discuss neurological side-effects with their patients. Even though they were aware of certain possible side-effects, they decided that they would not tell their patients, because they were concerned that the patients might refuse the treatment.[763] In other words, it had not been shown that adequate disclosure would have led the learned intermediaries to disclose the information. Although not pointed out *expressis verbis*, it seems that the independent judgment of the defendant doctors intervened in the chain of causation between the manufacturer and the consumer, causing the plaintiff's action to fail on this basis.[764] A similar result was found, arguably, in *Rothwell v. Raes*[765], where the warning given to physicians by Connaught Laboratories about side-effects inherent in a multi-purpose vaccine designed to give protection against pertussis (whooping cough) was found inadequate. The infant plaintiff showed signs of developmental abnormality, which might have been attributable to the vaccine. While Osler, J. followed *Buchan* in presuming that the physician would have warned of the risks if the pharmaceutical company had warned the physicians adequately, he concluded on the evidence that the presumption was not overcome, because both physicians involved had made it plain that

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[762] Davidson v. Connaught Laboratories at 277.
[763] *Ibid.*
[764] Peppin, at 512.
[765] (1989) 54 D.L.R. (4th) 193 at 339, affirmed (1991), 76 D.L.R. (4th) 280.

it was not their practice to discuss the risks of grave happenings such as befell their patient in this case.

It will be remembered that according to the rationale set out in the more recent decisions of *Buchan*[766] and *Hollis*[767], negligent conduct by the intervening physician does not automatically break the causal sequence shown by the plaintiff as an independent cause, which then necessarily relieves the manufacturer from liability. It is more a matter of weighing all the available evidence in the circumstances at hand, as put forward by the defendant, to determine if such a conclusion can be drawn in the particular case.[768] As a result the pharmaceutical company may be free of liability because of the non-disclosure practice of the physician. Consequently the possibility of harm-avoidance has been minimised and whatever deterrent effect tort law has is lost.[769] The patient is denied compensation from the company that created the harm, though the possibility of suing the

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[766] *Buchan* at 30.
[767] *Hollis* at 40-42.
[768] Excursus: These circumstances lead to another relevant issue. It is important to discover, what kind of influence the learned intermediary rule has regarding the quality of the warning duty of the learned intermediary. On the one hand the learned intermediary has his own instruction duty in informed consent cases. On the other hand he is the second link in the warning chain after the manufacturer, who can exceptionally discharge his duty towards the consumer by providing the learned intermediary with the necessary information.
This poses the question, whether there is any difference in the warning of the learned intermediary, when he gives his patient full disclosure or when he provides the patient with the information given by the manufacture? If he were only the mouthpiece for the pharmaceutical companies, he would not be liable for misinformation. But this is not the case here, because this does not relieve him from his own duty, which perhaps even forces him to an additional obligation, namely to prove the information given from the manufacturer.
This exactly shows the distinction between the quality of the warnings in either relationship. In the ideal case the learned intermediary passes the filtered warning on to the patient, adjusted to his particular needs. This means the information passed on can be additionally, but can also be fully, absorbed in the doctor's warning.
Who will in this situation be able to prove, that the hypothetical possibility of the learned intermediary's not warning according to his disclosure practice would have caused the injury anyway? Which part of the doctor's warning would it be that has to be shown as not missing according to the defendant's arguments, so that the plaintiff would have a chance of winning his action against the manufacturer?
[769] Peppin, at 515.

non-disclosing doctor remains open to him. The plaintiff will only be successful in his claim against his physician, though, if the materiality of the risk can be demonstrated, seemingly according to the higher standard of informed consent rather than according to the very low probabilities in the drug products liability cases, and if causation can be demonstrated under the contextual reasonable person standard established in *Reibl*.[770]

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[770] *Ibid.*

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