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Safety Warnings: Do They Grant an Indulgence from Product Liability?[1]

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Abstract
This article examines whether safety warnings can excuse or neutralize product defects under strict product liability. It addresses a persistent tension at the heart of modern product liability law: whether risk may be shifted to consumers through disclosure, or whether certain risks must remain with the producer irrespective of warning. The analysis proceeds from the premise that product liability is organized around defectiveness rather than fault. Within the European Union, defectiveness is determined by reference to the level of safety the public is entitled to expect, taking into account all relevant circumstances, including the product's presentation. Safety warnings, therefore, form part of the defectiveness inquiry, but their precise legal function remains contested. To clarify this function, the article combines doctrinal analysis of European Union legislation and case law with comparative insights drawn from the United States, England, and Canada. Particular attention is paid to the tripartite distinction between manufacturing defects, design defects, and failure-to-warn defects, which, while not formally embedded in European Union law, provides an analytically useful framework. The main conclusion is that warnings cannot be considered a general basis for exemption from liability. They cannot cure manufacturing defects, as this would undermine the regime's strict character by replacing the right to a safe product with a mere right to be informed of risks. In the context of design defects, the role of warnings is more limited and conditional. Where a reasonable alternative design exists, a warning cannot substitute for a safer design. Only where risks are irreducible, and no safer design is feasible, may an adequate warning suffice to render the product non-defective. Even then, warnings remain an imperfect safety mechanism, constrained by their dependence on user attention and behaviour. The article concludes that warnings are a necessary but inherently limited tool of risk regulation. They inform the assessment of defectiveness

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and may affect the apportionment of responsibility, but they cannot legitimize avoidably unsafe products.

Keywords: *product liability; non-contractual liability; civil liability; safety warnings; adaptation to EU law; defectiveness.*

Попередження про небезпеку: чи дають вони індульгенцію від відповідальності за дефектну продукцію?

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Анотація

У статті розглянуто можливість попередження про ризики виправдати або нівелювати дефектність продукції в межах режиму суворої відповідальності за шкоду, завдану дефектом продукції. Це стосується проблеми, що лежить в основі сучасного права відповідальності за продукцію: чи може ризик бути перекладений на споживача шляхом розкриття інформації, чи ж певні ризики мають залишатися на стороні виробника незалежно від наявності попередження. Дослідження ґрунтується на тому, що недоговірна відповідальність за дефектну продукцію організована навколо категорії дефектності, а не вини. У праві Європейського Союзу дефектність визначається через рівень безпеки, на який суспільство вправі обґрунтовано розраховувати, зважаючи на всі релевантні обставини, серед яких – презентація продукції. Відтак попередження є складовим елементом оцінки дефектності, однак їх достеменне правове значення залишається дискусійним. З метою з'ясування ролі попереджень у статті поєднуються доктринальний аналіз законодавства та судова практика Європейського Союзу з порівняльно-правовими спостереженнями права Сполучених Штатів, Англії та Канади. Особливу увагу приділено трикомпонентному поділу дефектів на виробничі, конструктивні та інформаційні, який, хоча формально й не закріплений у праві Європейського Союзу, однак на практиці виконує важливу аналітичну функцію. Основний висновок полягає в тому, що попередження не можуть вважатися загальною підставою звільнення від відповідальності. Вони не можуть усунути виробничі дефекти, оскільки це підривало б саму природу суворої відповідальності, замінюючи право на безпечний продукт правом бути поінформованим про небезпеку. У випадку конструктивних дефектів роль попереджень є більш нюансною та залежить від обставин. Якщо існує розумна альтернативна конструкція, попередження не може

замінити собою безпечніший дизайн. Лише за відсутності технічно та економічно здійсненної альтернативи належне попередження може забезпечити відповідність продукту вимогам безпеки. Водночас попередження залишаються недосконалим інструментом забезпечення безпеки, ефективність якого залежить від уваги та поведінки користувача. У підсумку доводиться, що попередження є необхідним, але внутрішньо обмеженим засобом регулювання ризиків. Вони враховуються при оцінці дефектності та можуть впливати на розподіл відповідальності, однак не здатні легітимізувати продукцію, небезпечність якої могла бути усунена.

Ключові слова: *відповідальність за дефектну продукцію; недоговірна відповідальність; цивільна відповідальність; попередження про ризики; адаптація до права ЄС; дефектність.*

Introduction

Can a warning excuse a defective product? More precisely, can a producer escape liability by alerting consumers to a risk that materializes?

A simple example captures the problem. A consumer purchases a chocolate bar containing nuts. While eating it, he encounters a fragment of a nutshell and breaks a tooth. The packaging, however, states: "May contain nut shells". Does this warning shield the producer from liability?

The example reveals a structural tension at the heart of product liability: can risk be shifted to the consumer through disclosure, or does the law insist that certain risks remain with the producer?

Similar tensions arise in other everyday contexts. Consider contraceptives accompanied by a notice that they do not provide 100 percent protection. If failure occurs, does the warning preclude liability? Or take children's products containing small detachable parts, often labeled with warnings about choking hazards.

These examples demonstrate that the legal effect of warnings cannot be reduced to a simple rule. Their role depends on deeper structural features of product liability, in particular the concept of defectiveness and the allocation of risk between producer and consumer. The analysis that follows seeks to clarify these issues by examining the function and limits of safety warnings within the framework of strict liability.

Materials and Methods

This study employs a doctrinal legal research methodology, complemented by structured comparative analysis. The selection of methods is determined by the nature of the research question, which concerns the legal significance of safety warnings within the framework of strict product liability. As the inquiry turns on the interpretation, coherence, and normative implications

of legal rules rather than empirical behavioral patterns, doctrinal analysis constitutes the principal methodological approach.

The doctrinal method is implemented through the systematic identification, interpretation, and critical evaluation of primary and secondary legal sources. The primary normative basis of the research consists of European Union legislation, in particular Directive (EU) 2024/2853 on liability for defective products [1] and Regulation (EU) 2023/988 on general product safety [2]. These instruments are analyzed using both textual and teleological interpretation, with particular attention to the provisions governing defectiveness, product presentation, and the role of warnings. Recitals are treated as authoritative interpretative aids, enabling reconstruction of the legislative intent and the internal logic of the regulatory framework.

Case law analysis constitutes the second core component of the methodology. Judicial decisions are examined as independent sources of law that concretize and operationalize statutory standards. The sample of cases was formed purposively, based on two cumulative criteria: (1) doctrinal relevance to the problem of safety warnings and defectiveness, and (2) jurisdictional representativeness. The selected decisions span multiple legal systems – including EU law, English law, United States law, and Canadian law – and reflect key doctrinal developments such as the consumer expectations test, the patent danger rule, the learned intermediary doctrine, and the relationship between design defects and warnings. This approach allows the study to capture both vertical coherence (between legislation and judicial interpretation within the EU) and horizontal coherence (across different legal traditions).

Comparative legal analysis is employed throughout as both a method and an analytical framework. The comparison operates along two axes. First, a vertical comparison assesses the consistency between EU legislative provisions and their interpretation by the Court of Justice of the European Union (CJEU). Second, a horizontal comparison contrasts the EU approach with common law doctrines, particularly those developed in the United States, which historically influenced European product liability law. The comparative method serves a functional purpose: it illuminates underlying structural principles and clarifies the limits of warning-based risk allocation.

Secondary sources – including monographs, comparative treatises, and peer-reviewed articles – are used to contextualise the analysis within broader academic debate and to reconstruct competing doctrinal positions. These sources also support the critical evaluation of existing interpretations and the formulation of normative conclusions.

Answering that question requires working through several layers of analysis. The paper proceeds in five parts. The first establishes the foundational character of product liability as a regime of strict liability – one in which the producer's fault is irrelevant, and the defectiveness of the product is the operative criterion. This principle has deep roots in American common law and is firmly enshrined in European Union law, most recently in Directive (EU) 2024/2853 on liability for defective products [1]. The second part examines how defectiveness is defined under EU law, with particular attention to the consumer expectations test that lies at the heart of the regime. The third part introduces a conceptual framework developed in American tort law – the tripartite distinction between manufacturing defects, design defects, and instruction defects – which, although not formally adopted in the EU Directive, continues to influence European legal thinking and will prove indispensable to the analysis that follows. The fourth part turns to safety warnings themselves: their legal function, the conditions under which they are required, and the doctrines – including the patent danger rule and the learned intermediary rule – that govern their adequacy. The fifth and concluding part of the analysis brings these threads together to answer the research question directly.

The central argument developed in this article is that safety warnings do not operate as a blanket exemption from liability. Their effect is contingent and context-dependent. They form part of the broader assessment of defectiveness, but they cannot, as a rule, legitimize a product that fails to meet the level of safety the law demands. The analysis that follows demonstrates how this conclusion emerges from the structure of strict liability, the normative nature of the consumer expectation test, and the limits inherent in risk communication as a regulatory strategy.

Results and discussion

1. Product Liability as a Strict Liability

Product liability is, at its core, a regime of strict liability [3-7]. Strictness is its most distinctive and consequential feature, and it sets product liability apart from the general law of tort, which ordinarily conditions liability on proof of fault [8]. In a conventional negligence action, a claimant must establish not only that she suffered harm caused by the defendant's conduct, but that the defendant failed to exercise the standard of care that a reasonable person would have observed, [9, Art. 4:101 and 4:102]. Product liability dispenses with that requirement entirely. The producer's fault – or its absence – is beside the point. What matters is not how the product was made, but what the product is: whether it is defective. The substitution of defectiveness for fault is the axis around which the entire regime turns, [10, p. 77].

This principle is firmly enshrined in EU law and has been maintained without interruption from the original Product Liability Directive of 1985 [11] through to its successor, Directive (EU) 2024/2853 [1]. Recital 2 of the current Directive states in terms that "liability without fault on the part of economic operators remains the sole means of adequately addressing the problem of fair apportionment of risk inherent in modern technological production" [1, rec 2].

The idea that a producer should be liable for a defective product regardless of fault did not originate in European law. It was first articulated – and most influentially developed – in American common law, from which European legislators consciously drew when constructing the 1985 Directive. The development of product liability in Europe as an autonomous area of law came considerably later, prompted by mass product disasters and the growing recognition that traditional tort responses were inadequate to address them [12, p. 20].

The intellectual foundations of strict product liability were laid in two landmark California cases. The first Escola v. Coca Cola Bottling Co. [13], decided in 1944. The facts were straightforward: a waitress was injured when a bottle of Coca-Cola, which had been delivered to her employer and left undisturbed for over thirty-six hours, exploded in her hand as she moved it from a case to a refrigerator. The bottle broke into two jagged pieces and inflicted a serious laceration, severing blood vessels, nerves, and muscles of the thumb and palm. The majority decided the case on conventional negligence principles. Justice Traynor, concurring, went further – and in doing so articulated what would become the foundational rationale for strict product liability.

In his concurring opinion Traynor J argued that negligence should no longer be the basis of a plaintiff's right to recover in such cases, and that a manufacturer ought to bear absolute liability whenever a defective product it placed on the market causes injury. The justification was grounded not in the producer's moral blameworthiness but in the practical logic of risk allocation. Three considerations drove the analysis. The producer is better positioned than any consumer to anticipate dangers, to guard against defects recurring, and to take corrective action across its entire production process. The injured consumer, by contrast, lacks any meaningful ability to inspect the product, to understand the manufacturing process, or to identify the source of a defect after the fact. And the cost of product-related injuries, if borne by the producer, can be spread across the price of goods and absorbed as an ordinary cost of doing business – a loss-spreading function that the individual victim is wholly unable to perform. On this reasoning, strict liability was not merely fair; it was the rational allocation

of a risk that is constant and general to the party best placed to manage and insure against it.

The second foundational decision is Greenman v. Yuba Power Products, Inc. [14], decided in 1963, in which the California Supreme Court – now with Traynor CJ writing for the majority – formally adopted strict liability in tort for defective products. The plaintiff had been seriously injured when a piece of wood flew out of a Shopsmith combination power tool and struck him on the forehead. Expert evidence established that inadequate set screws had been used to hold parts of the machine together, so that normal vibration caused the tailstock to move and release the workpiece. The Court held that proof of negligence was unnecessary. Reaffirming and extending the reasoning of Escola, it grounded strict liability in a straightforward principle of cost allocation: the losses caused by defective products should be borne by those who place such products on the market, not by the individuals who are powerless to protect themselves against them. A consumer who uses a product in the manner it was intended to be used, and is injured by a defect of which she was unaware, has done everything that could reasonably be expected of her. The producer, having placed the product into commerce and being best situated to know and address its dangers, is the appropriate party to bear the consequences when it falls short of the safety it implicitly represents.

The rationale that emerges from these decisions – and that underlies the EU legislative framework as well – rests on three interlocking considerations. The first is informational asymmetry: the producer knows, or is best placed to know, the risks inherent in its product, while the consumer does not and cannot. The second is risk management capacity: the producer is able to anticipate hazards, improve manufacturing processes, and take preventive measures that the consumer is powerless to take. The third is loss-spreading: the producer can insure against the risk of product-related injury and distribute that cost across the price of its goods, converting what would otherwise be a catastrophic individual loss into a diffuse and manageable social cost.

2. Defining Defectiveness

If product liability dispenses with fault, it must rest on a different organizing concept. That concept is *defectiveness* [12, p. 50; 15, Ch. 10]. It is the pivotal criterion that triggers liability and, at the same time, the principal filter through which claims are assessed. Yet, despite its centrality, defectiveness remains a nuanced and, at times, elusive notion [12, pp. 50-61; 16-18].

The starting point is the statutory definition. Under Art. 7(1) of Directive (EU) 2024/2853, a product is defective "where it does not provide the

safety that a person is entitled to expect or that is required under Union or national law". This formulation reflects a deliberate choice. The Directive does not ask whether the producer acted carefully, nor whether the product performs its intended function. Instead, it focuses squarely on *safety*. As the recitals clarify, the relevant benchmark is not fitness for purpose, but the absence of the level of safety that the public is entitled to expect, [1, rec. 30].

This distinction is not merely semantic. A product may be perfectly unfit for its purpose without being defective in the sense of product liability. A blunt kitchen knife is a familiar illustration: it fails to cut, yet it does not endanger the user. By contrast, a knife whose blade detaches during normal use is defective, because it creates an unacceptable risk of harm, [12, p. 50]. The law of product liability is therefore not concerned with disappointed expectations of utility, but with compromised expectations of safety.

In EU the core test underpinning this assessment is commonly described as the *consumer expectation test*. However, that label requires careful handling. The expectations in question are neither subjective nor empirical. The Court of Justice in *Boston Scientific Medizintechnik* (Joined Cases C-503/13 and C-504/13), emphasised that the benchmark is not the expectations of a particular user, but the *reasonable expectations of the public at large,* [19, paras. 37-38]. Therefore, the standard is *objective and normative* [12, pp. 50-53]. Courts are not bound by what consumers actually expect in practice, nor by prevailing market standards. Instead, they must determine – often with a considerable margin of appreciation – the level of safety that *ought* to be expected in a given context.

This normative dimension cuts both ways. On the one hand, it prevents liability from being driven by unrealistic or uninformed expectations. On the other, it allows courts to demand higher levels of safety than those reflected in existing practices or regulatory minima. The standard is thus dynamic. It evolves with technological progress, societal attitudes to risk, and the nature of the product in question.

Article 7(2) of the Directive provides a non-exhaustive list of circumstances to be taken into account when assessing defectiveness. Two features of this list merit particular attention for the purposes of the present analysis. The first is the inclusion of the product's presentation – which, as the commentary confirms, must be understood broadly to encompass marketing, advertising, packaging, instructions, and warnings [12, p. 56]. The manner in which a product is communicated to the public is therefore directly relevant to the assessment of defectiveness: inaccurate, incomplete,

or missing information will be taken into account and may, in appropriate cases, itself render a product defective [12, pp. 56-57]. The second is the reference to "reasonably foreseeable use", which Art. 7(2)(b) and Recital 31 make plain encompasses not only the product's intended use but also foreseeable *misuse* that is not unreasonable in the circumstances – such as the foreseeable behaviour of a distracted machine operator, or the foreseeable behaviour of children.

A useful bridge between the Product Liability Directive and the broader EU safety framework is provided by Regulation (EU) 2023/988 on general product safety [2]. While the Directive determines when a producer is liable, the Regulation defines what it means for a product to be safe in the first place. Under Art. 3(2), a product is safe if, under normal or reasonably foreseeable conditions of use, it presents no risk or only minimal risks compatible with its use. The assessment is similarly contextual and multifactorial, taking into account, inter alia, the product's characteristics, presentation, instructions, warnings, and the categories of consumers exposed to it (Art. 6). This alignment is not coincidental. The factors used to assess safety under the Regulation closely mirror those relevant for determining defectiveness under Art. 7 of the Directive. The two instruments thus operate in tandem: the Regulation articulates *ex ante* safety expectations, while the Directive enforces them ex post through liability. This conceptual continuity reinforces the centrality of safety – rather than fault – as the organizing principle of EU product liability law and provides an important interpretative lens for evaluating the role of warnings within that framework.

The notion of *risk* is particularly instructive for the present inquiry. Regulation (EU) 2023/988 defines risk as "the combination of the probability of an occurrence of a hazard causing harm and the degree of severity of that harm" (Art. 3(4)). This definition makes clear that safety is not an absolute concept, but one that depends on both the likelihood and the gravity of potential harm. The case law of the Court of Justice of the EU (CJEU) confirms that this calibration has direct implications for the standard of safety expected. In *Boston Scientific Medizintechnik*, concerning implantable cardioverter defibrillators, the Court emphasised that, given the function of such devices and the vulnerability of the patients concerned, the safety expectations are particularly high, [19, para. 39]. The logic is straightforward: the greater the potential harm, the more demanding the safety standard.

A similar approach can be observed in common law, where the Supreme Court of Canada in *Hollis v. Dow Corning Corp.* [20] voiced the same idea in the context of breast implants.

The Directive (EU) 2024/2853 resists any mechanical reliance on regulatory compliance. The newly introduced "safety required by law" test might suggest that a breach of safety rules automatically renders a product defective. Yet, as Rimkutė has shown, a closer reading reveals a more calibrated approach. Where a product violates mandatory safety requirements that are directly linked to the harm suffered, this may establish defectiveness or at least give rise to a presumption thereof, [10, pp. 84-85]. In other situations, compliance or non-compliance with regulatory standards is merely one factor among many. Not every regulatory breach translates into a lack of safety, and conversely, compliance does not guarantee that a product meets the level of safety the public is entitled to expect.

3. Three Types of Defects

The analysis of whether a safety warning can make up for a product defect depends, in no small part, on the type of defect in question. EU law, as seen above, does not formally distinguish between different categories of defectiveness – the Directive operates through the single, unified criterion of the safety the public is entitled to expect. Yet the categories developed in American tort law have not remained entirely alien to European legal thinking.

American tort law distinguishes between three types of product defect: manufacturing defects, design defects, and instruction defects (the last of which is also referred to as warning defects or failure-to-warn) [15, Ch. 10-12; 21, Ch. 5-8]. This tripartite framework was developed through case law and has since been expressly codified in section 2 of the Restatement (Third) of Torts: Products Liability (1998). Each category captures a distinct mode of product failure and attracts a distinct legal test.

A *manufacturing defect* arises when a specific unit of a product departs from its intended design, even though all possible care was exercised in its preparation and marketing [22, para. 39]. The product, as designed, may be perfectly safe; the problem lies in its execution. A bottle of Coca-Cola that explodes in a waitress's hand is the paradigm case: the design of the bottle was not at fault, but this particular unit was defective in manufacture. The applicable test is straightforward: the product failed to conform to its own intended specifications.

It is in the context of manufacturing defects that the strict character of product liability reveals itself most starkly. The cause of the manufacturing defect is legally irrelevant. Whether the defect arose from an error in the production process, from defective raw materials supplied by a third party, or from some unknown cause that cannot be identified at all – the producer

is liable. As Justice Traynor observed in his celebrated concurrence in *Escola*, the injury from a defective product "does not become a matter of indifference because the defect arises from causes other than the negligence of the manufacturer, such as negligence of a submanufacturer of a part whose defects could not be revealed by inspection, or unknown causes that even by the device of *res ipsa loquitur* cannot be classified as negligence of the manufacturer" [13]. The producer cannot exculpate itself by demonstrating that it exercised all possible care. Because the defect is measured against the manufacturer's own design, there is no balancing of costs and benefits, nor any inquiry into whether a safer alternative was available. Liability is, in this respect, as strict as strict liability can be.

A *design defect* arises when the product conforms precisely to its intended design, but the design itself is unreasonably dangerous. Unlike a manufacturing defect, which affects individual units, a design defect inheres in every unit of the product – it is a systemic rather than a one-off failure. The definition in the Third Restatement identifies a design defect as arising when the foreseeable risks of harm imposed by the product could have been reduced or avoided by a reasonable alternative design, and the absence of that alternative renders the product not reasonably safe [22, para. 39]. Two tests have been developed in American jurisprudence to establish design defectiveness. The first is the *consumer expectations test:* a product is defective in design if it fails to perform as safely as an ordinary consumer would expect when used in an intended or reasonably foreseeable manner. The second is the *risk-utility test:* even if the product meets ordinary consumer expectations, it may nonetheless be defective in design if the plaintiff can show that its design caused the injury and the defendant cannot establish that the benefits of the challenged design outweigh its risks Barker v. Lull Engineering Co. [23]. California courts, in Barker, articulated these as alternative rather than cumulative tests – a plaintiff may succeed under either.

Embedded within the risk-utility test is the doctrine of *reasonable alternative design* [24; 25], which has become the dominant approach in American design defect litigation. The doctrine holds that a plaintiff alleging a design defect must ordinarily demonstrate that a safer alternative design was available and feasible – technically and economically – at the time of manufacture. This requirement prevents design defect liability from collapsing into a form of absolute liability: the mere fact that a product causes harm does not establish that its design was defective if no practicable safer design existed. Conversely, where a reasonable alternative design was available, and the manufacturer chose not to adopt it, the manufacturer cannot escape liability by warning users of the dangers inherent in the existing design.

An *instruction defect*, or failure-to-warn, arises when a product – sound in both manufacture and design – is nonetheless rendered unsafe by the absence or inadequacy of warnings or instructions concerning its dangers. This category acknowledges that even a properly manufactured and well-designed product may pose risks of which the user is unaware and against which a warning would enable the user to protect herself. The applicable test focuses on whether the manufacturer knew or should have known of the relevant risk, whether the risk was latent rather than obvious, and whether an adequate warning would have been provided to a reasonable user. These requirements are examined in greater detail in Part 4.

Neither the 1985 Directive nor the new one adopts this tripartite structure. The English court in A v National Blood Authority made this explicit, rejecting both parties' attempts to characterise the infected blood at issue as either a manufacturing or design defect, and holding that "there is no place for them in the Directive" [22, para. 39]. The court instead formulated its own distinction – between *standard products* and *non-standard products* – finding this a more tractable framework for applying Art. 6 of the 1985 Directive. A non-standard product differs from the product as the manufacturer intended it to be; a standard product conforms to the manufacturer's design. This distinction, as Burton J acknowledged, effectively captures much of the same ground as the American manufacturing/design dichotomy, without importing the doctrinal baggage that accompanies it in US jurisprudence [22, para. 41].

Yet the influence of American categories has not been entirely excluded. As Machnikowski's commentary observes, notwithstanding the court's formal rejection of the tripartite approach, "legislative and judicial practice in the Member States is influenced by the American approach" [12, p. 53]. In practice, courts in EU member states tend to apply the consumer expectations test to manufacturing defects, while bringing additional considerations – including elements of a risk-utility analysis – to bear on design and instruction defects [12, p. 53]. The categories thus operate informally, shaping the practical application of the unified EU standard even where they have no formal doctrinal standing.

This matters for the present analysis. The question of whether a safety warning can make up for a product defect does not admit of a single answer if the type of defect is left unspecified. The answer differs – sharply and for principled reasons – depending on whether one is dealing with a manufacturing defect, a design defect, or a warning defect.

4. The Role of Safety Warnings

Safety warnings are one of the circumstances to be taken into account when assessing the defectiveness of a product under EU law. They are most

directly relevant to what American tort law would classify as instruction defectiveness – the third category of the tripartite framework examined in the preceding section. Yet warnings occupy an ambiguous position in the law more generally. A product that carries no warning of a known and non-obvious danger may be defective for that very reason. At the same time, a warning is not a pass permitting the producer to place an unsafe product on the market. Understanding the role of warnings in product liability, therefore, requires examining, in turn, the conditions under which warnings are legally required, the standards of adequacy they must meet, and the inherent limitations of warnings as an instrument of consumer protection.

4.1. Warnings as a Component of the Product

Under Regulation (EU) 2023/988 on general product safety, manufacturers are required to ensure that their products are accompanied by clear instructions and safety information in a language accessible to consumers, wherever the product cannot be safely used without such information [2, Art. 9(7)]. Warnings feature expressly among the aspects relevant to assessing whether a product is safe [2, Art. 6(1)(d)]. This reflects a broader principle confirmed in the academic commentary: the presentation of a product must be taken in its broadest sense, encompassing not only its physical design but also its marketing, packaging, labeling, instructions, and warnings, and the product must be assessed as a whole in its entirety [12, p. 56]. Inaccurate, incomplete, or altogether absent information is taken into account in the safety assessment and may, in appropriate cases, itself be the ground on which a product is found defective. In the case of inherently dangerous products – pharmaceuticals, complex machinery, products intended for vulnerable groups – information about foreseeable risks is essential to the safety assessment, and its absence will weigh heavily against the producer [12, p. 56-57].

4.2. The Patent Danger Rule

A warning need not be given in respect of dangers that are patent, open, and obvious to any reasonable user. This is the *patent danger rule*, and its rationale is straightforward: a warning that tells the user nothing she did not already know adds nothing to her safety. Where a danger is readily apparent as a matter of common sense, no duty to warn arises because no benefit would be gained by requiring one. Conversely, the open and obvious defence should not apply where there are aspects of the hazard that are concealed or not reasonably apparent to the user.

Although *Darby v National Trust* [26] arose outside the products liability context, it remains one of the clearest judicial illustrations of the patent

danger principle in English tort law. In that case, the claimant's husband drowned while swimming in an unsupervised pond on National Trust land, and his widow brought a claim under the Occupiers' Liability Act 1984, arguing that the Trust had failed in its duty of care towards recreational visitors. The Court of Appeal dismissed the claim, holding that the risk of drowning in a natural pond was a patent, self-evident danger which any reasonable adult would recognise without the need for a warning. "One or more notices saying 'Danger No Swimming' would have told Mr Darby no more than he already knew" [26, para. 26]. Therefore, the Court found that "It cannot be the duty of the owner of every stretch of coastline to have notices warning of the dangers of swimming in the sea. If it were so, the coast would have to be littered with notices in places other than those where there are known to be special dangers which are not obvious" [26, para. 27].

About products specifically, the rule is clearly illustrated by *Bogle v. McDonald's Restaurants Ltd.* [27], in which the English court considered claims brought by consumers who had suffered scalding injuries from hot drinks served at McDonald's restaurants. The drinks were served at temperatures between approximately 79 and 90 degrees Celsius – temperatures at which contact with skin for little more than a second would cause a deep-thickness burn. The claimants alleged, among other things, that McDonald's had been negligent in failing to warn of the risk posed by such temperatures. The court rejected this. Whether McDonald's had been negligent in failing to warn depended on an objective assessment of all the circumstances, including the customers' own appreciation of the risk. The court was satisfied that those who purchased coffee and tea could reasonably be taken to know that such drinks are served at temperatures capable of causing serious injury if spilled – this was a risk the public already appreciated. There was accordingly no duty to warn of a risk the consumer already understood.[2]

4.3. Requirements of an Adequate Warning

The content and intensity of the duty to warn vary with the level of danger the product presents in ordinary use. Where significant dangers attend the ordinary use of a product, a general warning will rarely suffice; the warning must be sufficiently detailed to give the consumer a full indication of each specific danger that may arise. The more serious the risk, the more exacting the requirement.

This principle, together with the related "learned intermediary" rule, is vividly illustrated by the decision of the Supreme Court of Canada in *Hollis v. Dow Corning Corp* [20]. In 1983, Ms Hollis underwent breast implant

[2] Yet compare the American case of *Liebeck v. McDonald's Restaurants, P.T.S., Inc.* [28].

surgery to correct a congenital deformity, acting on the advice of her surgeon, Dr Birch, who gave her no warning of the risks of post-surgical complications or of the possibility that the implants might rupture inside her body. In 1985, she noticed a lump and pain in her right breast; a subsequent operation revealed that the right implant had ruptured and that silicone gel had migrated. Her condition worsened after the removal of the implants. Crucially, Dow Corning had been aware since at least 1979 that implant ruptures could cause adverse reactions from loose gel, yet its warnings to physicians in 1976 and 1979 made no reference to these consequences, and attributed rupture only to abnormal squeezing or trauma. The Court of Appeal found Dow liable for failing to warn adequately of the risk of rupture, and the Supreme Court upheld that finding.

The Court emphasized that all warnings must be reasonably communicated and must clearly describe the specific dangers arising from the ordinary use of the product. For medical products designed for bodily implantation – given the intimate relationship between such products and the consumer's physical integrity – the standard of care in warning is necessarily high, imposing a heavy obligation on the manufacturer to ensure that all relevant risks are clearly, completely, and currently disclosed.

Hollis also examined the "learned intermediary" rule, which operates as an exception to the general principle that the duty to warn runs directly from the manufacturer to the ultimate consumer. In certain circumstances – typically where a product is highly technical and intended to be used only under expert supervision, or where the structure of its distribution makes direct communication with the end user unrealistic – a manufacturer may discharge its informational duty by warning a knowledgeable intermediary rather than the consumer. The paradigm case is the prescription pharmaceutical dispensed through a physician: the manufacturer needs to warn only the prescribing doctor, who acts as a learned intermediary between manufacturer and patient. The rationale is that the intermediary is best placed to assess both the properties of the product and the susceptibilities of the individual user, and to transmit appropriate information accordingly.

The rule is, however, strictly conditioned. It presupposes that the intermediary is genuinely learned – fully apprised of all relevant risks to a degree approximating the manufacturer's own knowledge. A manufacturer cannot claim the benefit of the rule where it has itself provided inadequate information to the intermediary, for that would defeat the very purpose the rule is designed to serve: ensuring that the consumer is fully informed. In *Hollis*, Dow Corning's warnings to Dr Birch were materially deficient –

understating both the likelihood and the consequences of rupture – and the learned intermediary rule accordingly provided no shelter. The primary duty to give a clear, complete, and current warning remained with the manufacturer, and it had not discharged it.

4.4. The Continuing Duty to Warn and Post-Sale Modifications

The duty to warn is a *continuing one*, extending not only to dangers known at the time of sale but also to dangers discovered after the product has been sold and delivered. It does not crystallize at the moment of sale and expire thereafter; it persists as new dangers come to the manufacturer's attention and as the product moves through the chain of distribution and use. This has particular significance in cases where a product is modified after sale in ways that create or amplify danger.

The point is strikingly illustrated by *Liriano v. Hobart Corp.* [29]. Luis Liriano, a seventeen-year-old employee, lost his right hand and forearm while feeding meat into a commercial meat grinder from which the safety guard had been removed by his employer. The grinder was manufactured and sold by Hobart in 1961, with a safety guard in place. Hobart subsequently became aware that a significant number of purchasers were removing the guards, and began issuing warnings about this danger from 1962, the year after the machine in question was manufactured and before it was acquired by Liriano's employer. At the time of the accident, the guard had been removed, Hobart had known of such removals, and the specific machine carried no warning. The district court dismissed Liriano's design defect claims but allowed his failure-to-warn claim to proceed; the jury found Hobart liable for failing to warn, apportioning five per cent of liability to Hobart and ninety-five per cent to the employer.

The New York Court of Appeals held that manufacturer liability may exist under a failure-to-warn theory in cases in which the substantial modification defence would preclude liability under a design defect theory. The reasoning was instructive. While it may be impossible to design a product to forestall all foreseeable post-sale modifications, the burden of warning against the dangers of such modifications is considerably lighter. The duty to warn is focused principally on the foreseeability of the risk and the adequacy and effectiveness of the warning – a far less demanding enquiry than the cost-benefit analysis required by a design defect claim. Hobart knew that guards were being removed; it was the party best placed to learn of such modifications and to pass warnings along the distribution chain. That knowledge generated a corresponding duty to warn, and its failure to affix any warning to the machine in question meant that duty went unmet.

4.5. The Inherent Limitations of Warnings

Even where a duty to warn exists and has been complied with, warnings are an imperfect instrument of consumer protection. Their efficacy as a means of preventing injury is inherently constrained, and this constraint has direct doctrinal consequences [30].

Twerski, Weinstein, Donaher, and Piehler identified the fundamental problem with clarity in their influential study of the use and abuse of warnings in products liability litigation [31, p. 509]. Warnings and knowledge of obvious dangers are of value only to users who are and can be attentive to them. But many product-related injuries arise precisely because of the inadvertent or impulsive acts of users who trip, fall, or momentarily lapse into forgetfulness. One of the principal functions of safety features – built into the design of the product itself – is to guard against exactly these foreseeable human failures. A warning cannot perform that function. It is addressed to the attentive, the informed, and the deliberate user; it has nothing to offer the user in the grip of an instinctive reaction, a moment of inattention, or a lapse of memory.

This does not mean that warnings are irrelevant to the reduction of risk. They often can and do bring the risk level down to an acceptable level, and in some cases, a well-crafted warning will be sufficient to render a product safe for its intended use [31, p. 509]. But warnings should not become the only focus of a product liability case. Where design can sharply curtail the level of danger at insignificant cost, the design modification is always the preferred alternative. The warning, in such a case, is not a substitute for a safer design – it is, at most, a complement to it.

The doctrinal picture that emerges from these authorities is therefore as follows. Warnings are a necessary but not sufficient condition of product safety. They need not address dangers that are patent. They are required wherever a product carries a non-obvious risk of which the consumer is unaware; they must be clear, specific, and proportionate in detail to the severity of the danger; and the duty to provide them is a continuing one. They may, in defined circumstances, be directed to a learned intermediary rather than the consumer directly. But they do not – and cannot – convert an otherwise unsafe product into a safe one simply by disclosing a risk. Whether a warning can go further still, and actually substitute for a product defect so as to defeat a liability claim, is the question to which the final section now turns.

5. Can Safety Warning Make Up for Manufacturing or Design Defects?

The preceding sections have established the architecture within which the central question of this paper must be answered. Product liability is a

regime of strict liability in which defectiveness, not fault, is the operative criterion. Defectiveness is assessed by reference to the safety the public is entitled to expect, taking into account the presentation of the product in its entirety, including any warnings accompanying it. Warnings are a legally recognized and in many cases, legally required component of a safe product, but they are an imperfect instrument whose efficacy is inherently constrained. The question that remains is the most important one: can a safety warning make up for a (another) product defect – and if so, under what conditions?

The answer is not uniform. It depends critically on the type of defect involved. As the analysis of the preceding sections has shown, manufacturing defects and design defects are conceptually distinct modes of product failure, and the role that a safety warning can play in relation to each is governed by different considerations and leads to different legal outcomes.

5.1. Safety Warning and Manufacturing Defect

A safety warning can never make up for a manufacturing defect. The proposition follows directly and necessarily from the strict character of product liability, and no departure from it is sustainable in principle.

A manufacturing defect, as established in Part 3, arises when a specific unit of a product departs from its intended design. The producer is liable because the product it placed on the market was not the product it intended to place on the market – it was, in the only sense that matters for the Directive, unsafe.

To permit the producer to escape that liability by pointing to a warning would be to negate the very essence of strict liability. If the producer could defeat a manufacturing defect claim by demonstrating that the product carried a warning – even a warning of the precise risk that materialized – the consumer's right to a safe product would be replaced by a right to be informed of the risk of receiving an unsafe one.

Recital 31 of Directive (EU) 2024/2853 confirms this analysis. It states in terms that "warnings or other information provided with a product cannot be considered sufficient to make an otherwise defective product safe, since defectiveness should be determined by reference to the safety that the public at large is entitled to expect" [1, rec 31]. The Directive is equally explicit that liability "cannot be avoided simply by listing all conceivable side effects of a product". These formulations are unequivocal: the presentation of a product, however comprehensive, however detailed, however carefully crafted, does not cure a defect. It is one circumstance among several relevant to the safety assessment; it is not a defence.

Return to the leitmotif example with which this paper opened. A chocolate bar carries the warning: "May contain nut shells". A fragment of shell is present in the bar and damages the consumer's tooth. The shell is not a feature of the bar's design – it is a contaminant, a departure from what the product was intended to be. It is, in the language of *National Blood Authority* case, a non-standard product: one that differs from the standard product the manufacturer intended to produce. The warning on the packaging cannot change that. The producer is liable because it placed a defective product on the market. The warning is beside the point.

5.2. Safety Warnings and Design Defects

The position in respect of design defects is more nuanced, and it is here that warnings may, in defined and demanding circumstances, play a more significant legal role.

As established in Part 3, the test for design defectiveness under US law – and the analogous enquiry under the EU consumer expectations test – asks whether the risks of harm inherent in the design could have been reduced or avoided by a reasonable alternative design. It is in the relationship between this enquiry and the role of warnings that the doctrinal complexity lies.

Machnikowski's commentary identifies the core principle with precision: whether a warning can render an otherwise unsafe product safe is not a question that admits of a uniform answer. In some cases, the provision of adequate information and warnings may be sufficient to bring the product within the safety expectations the public is entitled to hold, on the basis that the more information is provided to the targeted public, the lower the safety expectations that group may reasonably be expected to retain [12, p. 57]. In other cases – and this is the more common outcome – a warning will not suffice, because the legitimate safety expectations of the public remain higher than the product, even with its warning, is capable of meeting [12, p. 57-58].

The decisive criterion, therefore, is whether a reasonable alternative design was available. Where no reasonable alternative design existed – where the product could not, given the state of technical knowledge and without disproportionate cost, have been made safer – a warning of the residual risk may be sufficient to discharge the producer's obligations. In such a case, the warning is not covering up a remediable defect; it is communicating an irreducible risk inherent in a design that could not have been improved upon. A producer of a condom that carries a clear and accurate statement that the product does not guarantee complete protection against pregnancy or disease is not thereby admitting a remediable defect; it is disclosing an

inherent limitation that no alternative design could have eliminated. The warning, in such a case, is a legitimate and legally sufficient response to the risk.

This conclusion is, however, subject to a demanding condition: the warning must itself be adequate. It must meet all of the requirements identified in Part 4 – it must be clear, specific, and sufficiently detailed to give the consumer a full understanding of the risk in question; it must be proportionate to the severity of the danger; and it must be communicated to the person who will actually be exposed to the risk, whether directly or, where the learned intermediary rule applies, through an appropriately informed professional. A warning that is vague, incomplete, or buried in a document the consumer is unlikely to read will not suffice.

Where, on the other hand, a reasonable alternative design was available– where the producer could have redesigned the product to eliminate or substantially reduce the risk at proportionate cost, and chose not to – a warning cannot substitute for that safer design. This follows from the same logic that underlies the strict character of product liability. The producer who had the means to make its product safer and declined to do so cannot discharge its responsibility to the injured consumer by pointing to a label. Recital 31 of the Directive confirms that the assessment of defectiveness takes into account the presentation of the product, but that warnings cannot render an otherwise defective product safe. Where a reasonable alternative design existed, the product remains defective notwithstanding any warning, because the public is entitled to expect the safer version that was achievable. As the academic commentary recognizes, a warning is insufficient where it is possible to produce a safer product without extra financial burden and without affecting the utility of the product [12, pp. 57-58].

This is precisely the reasoning that animated the Massachusetts Supreme Judicial Court in *Uloth v. City Tank Corp*. [32]. The plaintiff was a refuse collection worker who lost his foot after it was caught in the shear point of a compaction mechanism on a refuse collection vehicle while he stepped onto the rear platform during the packing cycle. The defendants argued that their primary obligation was to warn of the danger, and that this discharged their responsibility entirely. The court declined to accept that proposition. A warning, it acknowledged, may in some cases reduce the likelihood of injury – but it cannot absolve the manufacturer or designer of all responsibility for the safety of the product where a modification to the design would have prevented the harm. The court was particularly attentive to the circumstances in which warnings fail altogether: where the user has no real alternative to engaging with the dangerous product, where the injury

arises from an instinctive reaction or a momentary lapse of attention, or where the risk manifests itself before any conscious response to a warning is possible. In all such cases, the warning is not merely insufficient – it is irrelevant to the outcome. The design modification, had it been made, would have prevented the injury regardless of the user's attentiveness. The warning could not have done the same. As the court stated plainly, where a slight change in design would prevent serious or fatal injury, the designer may not avoid liability simply by warning of the possible harm.

5.3. The Relevance of Warnings to Comparative Fault

The conclusion that a warning cannot substitute for a remediable design defect does not mean that warnings become legally irrelevant wherever a design defect claim succeeds. On the contrary, a warning may remain highly material in a distinct and important register: that of comparative fault (See: [33; 34]).

Article 13(2) of Directive (EU) 2024/2853 provides that the liability of an economic operator may be reduced or disallowed where the damage is caused both by a defect in the product and by the fault of the injured person or of any person for whom the injured person is responsible. Where a product carries an adequate safety warning that the injured person read, or ought to have read, and the injured person nonetheless proceeded to use the product in a manner the warning expressly cautioned against, that conduct may constitute contributory fault on the part of the injured person. In such circumstances, the liability of the economic operator – though not extinguished – may be reduced proportionately.

This is a significant qualification. A warning that cannot cure a design defect may nonetheless affect the apportionment of responsibility for the injury that results from it. The producer who designs a product with a remediable defect and fails to adopt the available safer design remains liable; but if the injured person disregarded a clear and adequate warning and acted negligently in doing so, the producer's liability may be reduced to reflect that shared responsibility. The warning, in this way, shifts from being a putative defence against liability to being a relevant factor in determining the extent of that liability.

The practical consequence is that producers operating under EU law have a dual incentive to provide adequate warnings even where a design defect may subsist. The first incentive is the possibility – in the narrow case where no reasonable alternative design exists – that adequate warnings may avert a finding of defectiveness altogether. The second is the more generally applicable possibility that adequate warnings, even where they do not defeat the defectiveness finding, may reduce the damages payable

by demonstrating that the injured person had been put on notice and bore some share of responsibility for the outcome.

Conclusion

The central question of this paper – do safety warnings exonerate the producer of a defective product from liability – can be answered as follows.

In the case of a manufacturing defect, the answer is no. To hold otherwise would dissolve the very foundation of the strict liability regime.

In the case of a design defect, the answer is more graduated. Where no reasonable alternative design was available and where the warning provided is genuinely adequate in content, clarity, and communication, the warning may be sufficient to bring the product within the safety expectations the public is entitled to hold, and no defectiveness finding will follow. Where, however, a reasonable alternative design was available, a warning cannot substitute for it: the product remains defective, and the producer remains liable. In that case, the warning is not irrelevant – it may bear on the question of comparative fault under Art. 13(2) of the Directive, potentially reducing the quantum of damages if the injured person disregarded it negligently. But it does not, and cannot, serve as an indulgence absolving the producer of responsibility for the harm its remediable design has caused.

The image with which this paper began captures the point neatly. A warning that a chocolate bar may contain nut shells cannot excuse the producer who places a nut shell in the bar. The consumer is entitled to a product that conforms to what it was intended to be, not merely to advance notice that it might not.

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