Two Roads Diverged in a Yellow Wood: The European Community Stays on the Path to Strict Liability

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Abstract

Part I of this Note will briefly outline Community policy on product liability as detailed by the Product Liability Directive, then review the development of product liability law in various Member States of the European Community. Part II will analyze how the concept of state-of-the-art highlighted tensions between a strict liability regime and a negligence regime in U.S. product liability. It will then review similar discord in the European Community caused by the development risk defense. Finally, Part III of this Note will argue that in contrast to the United States, the European Community has thus far chosen to stay true to the strict product liability label in its implementation of the development risk defense.
NOTES

TWO ROADS DIVERGED IN A YELLOW WOOD: THE EUROPEAN COMMUNITY STAYS ON THE PATH TO STRICT LIABILITY

Josephine Liu*

INTRODUCTION

Reginald Payne, sixty-three, was found dead at the foot of cliffs days after his wife, Sally was found suffocated in their home in Cornwall. Payne was prescribed Prozac to treat the depression that had developed after his retirement. On the eleventh day of his Prozac treatment, Payne suffocated his wife then threw himself off a cliff near their home. The three surviving sons of Reginald and Sally Payne have filed a product liability lawsuit before the British High Court against Eli Lilly, the manufacturer of Prozac. Hundreds of similar cases have been brought against

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2. See Verkaik, supra note 1, at 3 (explaining Payne had developed depression after retiring from his job as teacher); Angela M. Walker, Rx: Take Two of These and Sue Me in the Morning: the Emergence of Litigation Regarding Psychotropic Medication in the United States and Europe, 19 ARIZ. J. INT'L & COMP. L. 775, 789 (2002) (stating Payne had been on Prozac treatment).

3. See Verkaik, supra note 1, at 3 (noting Payne's homicidal and suicidal behavior manifested eleven days after he started taking Prozac); Walker, supra note 2, at 790 (pointing out that Payne killed himself and his wife eleven days after he started taking Prozac).

4. See Verkaik, supra note 1, at 3 (remarking that Paynes' sons plan to go to British High Court in 2001 to prove that Prozac was to blame for their parents' death); Walker,
Eli Lilly and other antidepressant manufacturers.\textsuperscript{5}

In the United States, a majority of courts hold that most therapeutic drugs, like Prozac, are unavoidably unsafe products that fall under the ambit of \textit{comment k},\textsuperscript{6} exempting them from strict product liability.\textsuperscript{7} The concern underlying the \textit{comment k} exception is the impact of imposing strict liability on the pharmaceutical sector and the deterring effect on innovation of new drugs.\textsuperscript{8} Under \textit{comment k}, manufacturers of drug products are held to a negligence standard rather than to strict liability.\textsuperscript{9}

\textsuperscript{5} See Walker, supra note 2, at 775 (observing hundreds of cases involving Prozac have been brought in United States and abroad); Andrew E. Falsetti, \textit{Fluoxetine-Induced Suicidal Ideation: An Examination of the Medical Literature, Case Law, and the Legal Liability of Drug Manufacturers}, 57 \textit{Food Drug L.J.} 273, 283 (reporting that hundreds of suits have been brought against Eli Lilly and other antidepressant manufacturers). Fluoxetine is the generic chemical name of Prozac. See Falsetti, supra at 274 (mentioning fluoxetine as chemical name of Prozac). See also, Prozac Prescribing Information, Eli Lilly & Co., at 1 \textit{available at} http://pi.lilly.com/prozac.pdf (2003) (copy on file with author) (noting fluoxetine is generic chemical name of Prozac). A comprehensive review of medical literature studying the link between fluoxetine and suicidal ideation is provided by Falsetti, who has a Pharm.D. degree. See Falsetti, supra (reviewing medical literature discussing relationship between fluoxetine and suicidal ideation). Falsetti concludes that medical literature does not support an association between fluoxetine and suicidal ideation. See Falsetti, supra at 280-83 (noting clinical trial data does not support link between fluoxetine and suicidal ideation).

\textsuperscript{6} See \textit{Restatement (Second) of Torts} [hereinafter \textit{Restatement (Second)}], cmt. k (pointing out that products, like drugs, are unavoidably unsafe). See also, Walker, supra note 2, at 780 (declaring that Prozac is unavoidably unsafe product); Falsetti, supra note 5, at 284 (reviewing cases against antidepressant manufacturers and noting courts have followed \textit{comment k} which imposes negligence standard for unavoidably safe products like Prozac).

\textsuperscript{7} See Walker, supra note 2, at 780 (citing \textit{comment k} of Section 402A of \textit{Restatement (Second)} for proposition that manufacturers are not liable for unavoidably unsafe products); JAMES A. HENDERSON & AARON D. Twerski, \textit{Products Liability, Problems and Process} 456 (4th ed. 2000) (1938) (explaining \textit{comment k} has been adopted in overwhelming majority of jurisdictions and imposes liability on drug manufacturers only if it fails to warn of defect).

\textsuperscript{8} See \textit{Restatement (Second)}, cmt. k (pointing to pharmaceutical sector as specific example of industry directly impacted by \textit{comment k}). See also, HENDERSON & TWERSKI, supra note 7, at 455-56 (commenting on discussions of America Law Institute in deciding whether to impose strict liability on pharmaceutical sector).

In the European Community ("EC"), product liability law is governed by the Product Liability Directive 85/374 ("Directive"), which imposes strict liability on manufacturers of defective products but allows an exception to liability for development risks. In the case of prescription drugs like Prozac, the manufacturer may escape liability under the development risk defense if the manufacturer can show that the defect was undiscoverable given the state of scientific and technical knowledge at the time the product was put into circulation. The implementation of the development risk defense in the EC has been quite contentious.

What is the difference between strict product liability and negligence in a design defect case? This classic doctrinal question has had product liability scholars pontificating and theorizing for decades. The move in the United States towards the

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10. See generally James Hanlon, European Community Law 3-4 (3d ed. 2003) (providing general information on European Community ("EC") and EC law); Chris Vincenzi & John Fairhurst, Law of the European Community 4-7 (3d ed. 2002) (discussing EC and laws pertaining to EC). The Treaty of Paris in 1951 and the Treaties of Rome in 1957 marked the beginning of efforts towards the integration of Europe, setting up the European Coal and Steel Community ("ECSC"), the European Economic Community ("EEC"), and the European Atomic Energy Community ("Euratom"). See Hanlon, supra at 3-4 (mentioning treaties setting up three Communities); Vincenzi & Fairhurst, supra at 4-7 (describing treaties unifying Western European). In 1965, the Merger Treaty further consolidated the institutions of the three Communities into one European Council, one European Commission, one European Court of Justice, and one European Parliament. See Hanlon, supra at 5 (discussing Merger Treaty); Vincenzi & Fairhurst, supra at 7 (noting simplification of Communities' institutional structure). The Treaty on European Union, signed in 1992 further unified Europe by creating the European Union. See Hanlon, supra at 9 (detailing creation of European Union); Vincenzi & Fairhurst, supra at 12-13 (explaining Treaty on European Union). For the sake of consistency, this Note will refer to the entity as the European Community.


12. See Directive, supra note 11, art. 7(e). See also Henderson & Twerski, supra note 7, at 706-07 (describing European Product Liability Directive).

13. See Walker, supra note 2, at 783 (noting development risk defense is application to product liability actions involving Prozac); Jane Stapleton, Products Liability in the United Kingdom: The Myths of Reform, 34 Tex. Int'l L.J. 45, 50 (1999) [hereinafter Stapleton, Myths of Reform] (commenting on importance of development risk defense to pharmaceutical industry).


Restatement (Third): Products Liability ("Restatement (Third)"") may cause some to wonder if such distinction matters.\textsuperscript{16} For product liability in the EC, the distinction between the strict liability and negligence regime is of critical importance.\textsuperscript{17}

Professor Anita Bernstein described the imposition of strict liability on the European Member States as a well-designed laboratory experiment for Americans to study the question of what strict liability means.\textsuperscript{18} Bernstein asserted that under the Directive, three parallel laboratory experiments will be run giving observers the opportunity to consider: (1) the shift from \textit{de facto} strict liability to \textit{de jure} strict product liability;\textsuperscript{19} (2) the move...
from a shifted-presumption approach to strict liability;\(^{20}\) and (3) the change from pre-Greenman and -Henningsen America to strict liability.\(^{21}\) Additionally, countries that do impose liability for development risk would constitute a laboratory by themselves in determining whether imposition of liability for unknown risks will give a different result from countries that allow the development risk defense.\(^{22}\) The European experiment is now well on its way and looks to be heading in the direction of strict liability.\(^{23}\)

Part I of this Note will briefly outline Community policy on product liability as detailed by the Product Liability Directive, then review the development of product liability law in various Member States of the European Community. Part II will analyze how the concept of state-of-the-art highlighted tensions between a strict liability regime and a negligence regime in U.S. product liability. It will then review similar discord in the European Community caused by the development risk defense. Finally, Part III of this Note will argue that in contrast to the United States, the European Community has thus far chosen to stay true to the strict product liability label in its implementation of the development risk defense.

I. DEVELOPMENT OF PRODUCT LIABILITY LAW IN THE EUROPEAN COMMUNITY

A. Product Liability Policy in the European Community

The Product Liability Directive was adopted in July 1985,\(^{24}\) establishing a community policy on product liability in the EC but leaving the specifics of implementation to the Member

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20. See Bernstein, supra note 15, at 212 (noting Britain shifts burden of proof to defendant once product defect is shown); Taschner, supra note 19, at 84 (stating Britain has reversed burden of proof).

21. See Bernstein, supra note 15, at 212 (stating less wealthy countries generally follow fault and warranty rules literally); Taschner, supra note 19, at 84 (noting Spain, before Consumer Protection Act of 1984, relied on traditional fault liability).

22. See Bernstein, supra note 15, at 213 (referring to Luxembourg); Linger, supra note 14, at 498-99 (noting Luxembourg rejected development risk defense).


The Directive did not preempt product liability law in the Member States, but instead, sought to supplement existing law to the extent that it was consistent with the Directive. Two basic goals of the Directive are discernable from the Preamble of the Directive: (1) to promote the free movement of goods by


26. See Directive supra note 11, at pmbl. The Preamble states in part:

Whereas under the legal systems of the Member States an injured party may have a claim for damages based on grounds of contractual liability or on grounds of non-contractual liability other than that provided for in this Directive in so far as these provisions also serve to attain the objective of effective protection of consumers, they should remain unaffected by this Directive whereas, in so far as effective protection of consumers in the sector of pharmaceutical products is already also attained in a Member State under a special liability system, claims based on this system should similarly remain possible.

Id. Member States are governed by Community law, the primary source of which comes from the Treaty of Paris and Treaties of Rome, as amended by subsequent treaties. See Hanlon, supra note 10, at 102 (stating primary source of Community law consists of three original treaties); Vincenzi & Fairhurst, supra note 10, at 180 (discussing role of Treaty of Paris and Treaties of Rome as primary source of law). Institutions set up under these treaties are given the power to pass secondary legislation — mainly decisions, directives, and regulation. See Hanlon, supra note 10, at 102-03 (discussing role of decisions, directives and regulations as secondary sources of Community law); Vincenzi & Fairhurst, supra note 10, at 36 (discussing secondary legislation, which comprise of decisions, directives, and regulations). Regulations are a detailed form of law which become valid in the Member States without further implementation. See Hanlon, supra note 10, at 104 (stating regulations are valid in Member States without further implementation); Vincenzi & Fairhurst, supra note 10, at 36 (stating regulations are binding and have general application). In contrast to regulations, directives are binding only as to the desired results and require implementation by Member States. See Hanlon, supra note 10, at 105 (discussing force of directives); Vincenzi & Fairhurst, supra note 10, at 37 (stating directives leave implementation to Member States). Decisions are acts of law that are binding and enforceable in its entirety upon those to whom it is addressed. See Hanlon, supra note 10, at 106 (describing decisions as binding and enforceable acts of law); Vincenzi & Fairhurst, supra note 10, at 38 (stating decisions are binding in its entirety and is addressed to person or Member State).


28. See Directive supra note 11, at pmbl. The Preamble states in part:

Whereas approximation of the laws of the Member States concerning the lia-
harmonizing national approaches among Member States;\(^2\)\(^9\) and (2) to protect consumers by establishing a strict product liability system.\(^3\)\(^0\)

1. Liability for Defective Products under the Directive

The Directive lays out strict product liability in twenty two articles and defines specific terms to clarify the Directive’s scope.\(^3\)\(^1\) Article 2 defines *product* as “all movables . . . even though incorporated into another movable or into an immovable.”\(^3\)\(^2\) Electricity is specifically included as a “product,”\(^3\)\(^3\) and while the original scope of the Directive did not include primary agricultural products, such items were defined as products after


\(^4\) See Freedman, supra note 29, at 8 (stating EEC Draft Directive on Product Liability set up strict liability system to protect consumers); Davis, supra note 29, at 332 (stating consumer well-being and protection is second goal of Directive).

\(^5\) See Directive, supra note 11, arts. 1-22 (setting out strict product liability in twenty-two articles and defining terms).

\(^6\) Id. art. 2 (defining product as all movables). In contrast to U.S. law, under the Directive, human blood and blood products would fall under “products.” See Hodge, supra note 17, at 51 (stating human products such as book, tissue and organs are “products” under Directive); George W. Conk, Is There a Design Defect in the Restatement (Third) of Torts: Product Liability?, 109 YALE L.J. 1087, 1089 (2000) (stating blood products are excluded from the Restatement (Third) entirely). In the United States, the vast majority of state legislatures have enacted shield statutes that protect sellers of blood from strict product liability. See Henderson & Twerski, supra note 7, at 105 (stating forty-nine states have enacted blood shield statutes); Conk, supra at 1094 (asserting forty-seven states have blood shield laws).

\(^7\) Directive, supra note 11, art. 2.
the "mad cow" crisis. Producer is defined broadly in Article 3 as the producer of a finished product, any raw material or a component part, and any person who presents himself as a producer by putting his name or mark on the product. In addition, anyone who imports a product that falls under Article 2 can also be held liable. Persons involved in the production chain, such as suppliers and retailers are not liable as long as they can identify a producer. According to Article 4, the injured person is required to prove: (1) the damage; (2) the defect; and (3) the causal link between the defect and the damage.

This defect is tied to consumer expectation and is defined


35. See Directive, supra note 11, art. 3 (defining producer). See generally Howells, supra note 17, at 30-32 (discussing scope of Article 3 in defining producer).


37. See Directive, supra note 11, art. 3, § 3. See also Culhane, supra note 25, at 45 (stating suppliers are treated as producers unless they can identify producer of product within reasonable time); Howells, supra note 17, at 31-32 (asserting supplier is liable unless he informs injured person identity of his own supplier within reasonable time). The general rule in the United States is that parties in the distributive chain are liable for strict product liability. See Henderson & Twerski, supra note 7, at 31 (noting parties down distributive chain are liable). See also Anderson v. Somberg, 338 A.2d 1 (N.J. 1975) (allowing plaintiff to join all members of distributive chain). Recent trends, however, have been to let retailers and wholesalers off the hook. See Henderson & Twerski, supra note 7, at 142 (discussing retailer and wholesaler liability). See also Morrison v. Sears, Roebuck & Co., 354 S.E.2d 495 (N.C. 1987) (holding that sellers are not liable for defective products sold in sealed containers or under circumstances in which seller could not inspect product).

38. See Directive, supra note 11, art. 4. See also, Simon Pearl, European Product Liability 42-43 (2000) (listing what claimant has to prove in strict liability case); Howells, supra note 17, at 35 (discussing plaintiff's case in context of Article 4).

in Article 6, Section 1 of the Directive. The Directive focuses on the lack of safety that a person, regardless of whether that person is producer or consumer, may expect from the product. Thus, an objective, rather than a subjective test is used. Article 6(1)(b), however, stipulates that the product must have been used in a reasonable way and (1)(c) includes the age of the product as an additional factor. Article 6(2) further carves out a “subsequent remedial measures” caveat, by providing that a product is not defective merely because a better product is subsequently put into circulation.

2. Defenses to Liability Under the Directive

Article 7 of the Directive sets out six defenses to strict prod-
uct liability. Sections (a)-(c), and (f) provide that a producer is not liable if: (a) he did not put the product in circulation; (b) there was no defect when the product was put into circulation by him; (c) he was not the producer; and (f) he was a component manufacturer and the defect was attributable to the product in which the component has been fitted. Section (d) accepts compliance with mandatory regulations issued by public authorities as a complete defense to strict liability.

The development risk defense, set out in (e), is the most controversial. Section (e) states:

The producer shall not be liable as a result of this Directive if he proves (e) that the state of scientific and technical knowledge at the time when he put the product into circulation was not such as to enable the existence of the defect to be discovered.

The development risk defense was inserted as an optional provision which may be derogated by Member States.

As of 1995, all Member States with the exception of France

46. See Directive, supra note 11, art. 7 (outlining defenses available under Directive).
47. See Directive, supra note 11, art. 7(a)-(c), (f) (exempting producer from liability if he did not put product in circulation, if product was not defective at time of circulation, if he was not producer, and if he was component manufacturer of defective product containing component). See also, Mildred, supra note 36, 437 (discussing six defenses available to defendant); HOWELLS, supra note 17, at 40-43 (outlining defenses available under Directive).
48. See Directive, supra note 11, art. 7(d) (exonerating producers from liability if they complied with "mandatory regulations"). See also, HOWELLS, supra note 17, at 42 (stating defect must have been due to compliance with mandatory standards). Compare U.S. product liability law outlined in Restatement (Third) § 4(b) which states that "a product's compliance with an applicable product safety statute or administrative regulation . . . does not preclude as a matter of law a finding of product defect." HENDERSON & TWERSKI, supra note 7, at 572 (quoting Restatement (Third) and stating that majority of states follow position set forth in § 4(b)).
49. See HOWELLS, supra note 17, at 39-40 (discussing controversy surrounding inclusion of defense); Christopher Hodges, Development Risks: Unanswered Questions, 61 Mod. L. Rev. 560, 560 (1998) [hereinafter Hodges, Unanswered Questions] (noting that development risks defense has aroused most interest); Linger, supra note 14, at 490 (commenting on controversial nature of development risk defense).
50. Directive, supra note 11, art. 7(e).
51. See Hodges, supra note 17, at 9 (noting that development risks defense is optional); Linger, supra note 14, at 478-79 (discussing optional development risk defense and proposing that defense become mandatory); Elizabeth C. Price, Toward a Unified Theory of Products Liability: Reviving the Causative Concept of Legal Thought, 61 TENN. L. REV. 1277, 1340 (1994) (mentioning development risk defense is one of two optional provisions from which Member States may derogate).
had taken measures to implement the Directive.\textsuperscript{52} Austria, Belgium, Denmark, Germany, Greece, Ireland, Italy, Netherlands, Portugal, Sweden and the United Kingdom included the development risk defense;\textsuperscript{53} Spain included the defense though excluded medicines, food or food products intended for human consumption from its ambit;\textsuperscript{54} and Finland and Luxembourg ex-

\begin{itemize}
  \item \textsuperscript{54} See Ley 22/1994, de 6 de Julio, Sobre Responsabilidad Civil por los Daños Causados por Productos Defectuosos [Law 22/1994 of July 6 on Civil Liability for Damages Caused by Defective Products], B.O.E., No. 1597, July 7, 1994, art. 6, § 1(e) [hereinafter Spanish Product Liability Act] (providing exception to liability for development risks); id. art. 6, § 3 (stating § 1(e) exoneration clause is not available for pharmaceutical products and food products intended for human consumption). See also Michael Ansaldi, The Spanish Products Liability Act of 1994, 2 ILSA J. Int'l & Comp. L. 371, 426-31 (1996) (providing translation of Spanish Liability Act).
\end{itemize}
cluded the defense altogether.\textsuperscript{55}

3. The Green Paper on Liability for Defective Products

In 1999, the European Commission adopted the Green Paper on Liability for Defective Products.\textsuperscript{56} The Green Paper, issued to stimulate public discussion, had two aims: (1) to gather information on the practical application of the Directive and determine if its objectives were met; and (2) to gauge reactions to possible revisions to the most sensitive points of the Directive.\textsuperscript{57} Among the issues considered were implementation of the development risks defense and consideration of its abolition.\textsuperscript{58} The Green Paper specifically requested input on whether removal of the development risk defense would discourage producers from innovation, citing concern for the pharmaceutical industry, and whether it would be feasible to insure against development risks.\textsuperscript{59} The Green Paper also asserted that whether or not to include the development risk defense delayed the adoption of the Directive by France.\textsuperscript{60} France ultimately joined the majority of Member States in allowing a development risk defense apart

\textsuperscript{55} See Tuotevastuulaki Annettu Helsingissä 17 Päivänä Elokuuta 1990 [Product Liability Act of 17 August 1990], amended by Law Number 99 of 8 January 1993 and Law Number 879 of 22 October 1993 [hereinafter Finnish Product Liability Act], § 7 (providing exemptions to liability); Loi du 21 avril 1989 relative à la responsabilité du fait des produits défectueux [Law of 21 April 1989 on the Civil Liability for Defective Products], amended by Law of 6 December 1989, art. 4 [hereinafter Luxembourg’s Product Liability Act] (listing grounds by which producer may be exonerated from liability). See also First Report, supra note 52, at 4 (noting national implementation of optional provisions); Unforeseen Risk Aversion: Christopher Hodges Analyses a Court Victory for UK Industry, FIN. TIMES, June 10, 1997, at 18 (stating development risk defense had been implemented by all member apart from Finland and Luxembourg with Spain excluding medicines and food products).


\textsuperscript{57} See Green Paper, supra note 56, at 2 (explaining objectives of Green Paper, which are to gather data on practical application of Directive to determine if goals were met and to gauge reactions to possible revisions of Directive).

\textsuperscript{58} See id. at 3 (remarking implementation of development risk defense and assessment of its possible abolition were considered).

\textsuperscript{59} See id. at 24-25 (reporting European Commission did not have all information required to determine whether liability for development risks would prove to be insurmountable to producers and requesting information on application of development risk defense with respect to impact on innovation and possibility of insurance).

\textsuperscript{60} See Hurd, supra note 27, at 61 (noting debate over possible inclusion of development risk defense held up harmonization process); French Failure to Implement Directive, BUS. L. BRIEF, Feb. 1, 1993 (stating French implementation of Directive had been stalled by disagreement over development risk defense).
from products derived from the human body.  

The European Commission's Report in 2000 considered reactions to the Green Paper. Specifically, the Report considered data from the five Member States that allowed partial or total liability for development risks. As of 2000, very little data was available to determine the practical impact of imposing liability for development risks. An updated report is expected in 2005.

In the meantime, the European Commission has appointed Lovells, an international business law firm, to conduct a study ("Study") to determine the practical effects of the Directive on product liability law in the EC. Twelve conclusions were made based on the Study. Lovell's determined that the number of product liability claims in the EC had increased noticeably in the last ten years. The increase in claims was mainly attributed to


63. See id. at 17-18 (reviewing information available with regard to five Member States that either did not adopt the development risk defense or did so with exceptions). Data from Finland, France, Germany, Luxembourg, and Spain were reviewed. Id.

64. See id. at 18. (declaring lack of data to determine impact of imposing liability for development risks).

65. See id. at 36 (noting European Commission will present another report in 2005).


67. See Lovell's Study, supra note 66, at 24-45 (summarizing findings and conclusions).

68. See Lovell's Study, supra note 66, at 31 (noticing increase in number of product liability claims in the last ten years); Meltzer, supra note 66, at 45 (reporting most participants of survey thought number of product liability claims had increased).
increased consumer awareness of rights, greater access to information, and media activity, although the Directive contributed as well.\textsuperscript{69} The Study also noted that product liability claims have generally become more successful in the past ten years, with the Directive contributing to that success.\textsuperscript{70} Overall, the Study reported that 66\% of all participants, 20\% of consumers, 66\% of producers, 86\% insurers, and 63\% of regulators, lawyer and academics, felt that the Directive struck an appropriate balance between consumer protection and maintaining incentives for innovation.\textsuperscript{71} The European Commission has undertaken a separate study to determine the economic impact of removing the development risk defense.\textsuperscript{72}


From the very beginning, there was a tension between the two institutions\textsuperscript{73} responsible for drafting the Directive:\textsuperscript{74} the European Commission,\textsuperscript{75} which advocated strict liability for con-
sumer protection, and the European Parliament, which voiced its discomfort in imposing liability for risks that the manufacturer could not have known about. In the end, a compromise was reached that provided the Article 7(e) "development risk" defense to the general rule of strict liability. Therefore, a manufacturer may escape liability by showing that given the existing scientific and technological knowledge at the time of the product's circulation, the defect could not have been discovered.

In a community of fifteen countries with legal systems that reflect a diversity of culture, an agreement was made to harmonize product liability law irrespective of the varying levels of consumer protection already established in each individual country. Where the Member States have diverged is in their imple-
mentation of the development risk defense. Two countries, Finland and Luxembourg, have chosen not to implement the defense while three countries, France, Spain and the United Kingdom have deviated from the rest of the Member States in their implementation of the defense.

1. Finland

Finnish product liability law grew from the contractual relationship between seller and buyer. Nordic countries like Finland adopted the *culpa* theory of contractual responsibility,

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83. See Report, supra note 62, at 16-17 (outlining varying implementation of development risk defense in Member States). See also Linger, supra note 14, at 491 (arguing that development risk defense should be mandatory in order to promote innovation).

84. See Finnish Product Liability Act, supra note 55, § 7 (exonerating producers from liability in certain situations but imposing liability for development risks); Luxembourg's Product Liability Act, supra note 55, art. 4 (allowing exceptions to liability but none for development risks). See also First Report, supra note 52, at 4 (noting Finland and Luxembourg excluded development risk defense).

85. See French Product Liability Act, supra note 61, art. 12 (exonerating producers from liability due to development risk); id. art. 13 (conditioning development risk defense on action by producer to make provisions to prevent consequence of defect); Spanish Product Liability Act, supra note 54, art. 6, § 1(e) (providing development risks defense); id. art. 6, § 3 (stating Section 1(e) exoneration clause is not available for pharmaceutical products and food products intended for human consumption); Consumer Protection Act, supra note 53, ch. 43, pt. 1, § 4(1)(e) (absolving producers of liability due to development risks). Strict liability for pharmaceutical products had existed since 1978 in Germany under the Pharmaceutical Products Act. See Gesetz über den Verkehr mit Arzneimitteln v. 24.8.1976 (BGBl. I S. 2445) in der Fassung der Bekanntmachung v. 19.10.1994 (BGBl.I S. 3018), zuletzt geändert durch Ges. v. 25. Februar 1998 (BGBl. I S. 374) [hereinafter Pharmaceutical Products Act]. See also Report, supra note 62, at 16-18 (noting exception to development risk defense in Germany); Taschner, note 36, at 27 (reporting Germany included development risk liability for every pharmaceutical producer regardless of fault). It is therefore not surprising that Germany excluded the development risk defense for pharmaceutical products. See Germany's Product Liability Act, supra note 53, § 15 (exempting products that fall under Pharmaceutical Products Act from provisions of Germany's Product Liability Act); Report, supra note 62, at 16-17 (noting exception to development risk defense in Germany). Germany's implementation of the development risk defense will not be discussed in this Note. For information on Germany's product liability law, see Manfred Wandt, *German Approaches to Product Liability*, 34 TEx. INT'L L.J. 71 (1999) (providing information on Germany's Product Liability Act and Pharmaceutical Products Act).

which is liability based on negligence on the part of the seller.\textsuperscript{87} Finnish product liability was made up of two components: (1) the manufacturer's obligation to make his product as safe as is reasonable possible given available technology; and (2) the manufacturer's obligation to warn potential buyers of inherent risks in the use of the product, known to the manufacturer but not the public at large.\textsuperscript{88} Finland implemented the Directive by adopting the Law of April 21, 1989 on the Civil Liability for Defective Products.\textsuperscript{89} In advocating strict product liability without an exception for development risks, the consumer movement argued that including the defense would allow manufacturers to raise the defense as a tactical move regardless of the merits.\textsuperscript{90} Consumer advocates asserted that justice would be hindered because consumers unable to foot the legal fees would drop suits or settle for less than reasonable amounts.\textsuperscript{91} In the end, the development risk defense was not included.\textsuperscript{92}

2. Luxembourg

Prior to implementation of the Directive, the contract law of warranty protected consumers from harmful products in Luxembourg.\textsuperscript{93} Sellers were required to guarantee against latent defects.\textsuperscript{94} The rule of privity governed claims brought for defects

\textsuperscript{87} See Hodges, supra note 17, at 293 (stating Nordic culpa theory of liability was based on seller negligence); Howells, supra note 17, at 154 (reporting consumers relied on negligence principles for product liability).

\textsuperscript{88} See Hodges, supra note 17, at 295 (describing two components of Finnish product liability — manufacturer's obligation to make product safe given available technology and obligation to warn of inherent risks in use of product).

\textsuperscript{89} See Finnish Product Liability Act, supra note 55 (providing strict liability for defective products in Finland). See Hodges, supra note 17, at 296 (noting implementing act and date on which legislation came into force); Pearl, supra note 38, at 11 (providing information on Finnish implementation of Directive).

\textsuperscript{90} See Howells, supra note 17, at 157 (describing arguments made by consumer movement).

\textsuperscript{91} See id. (outlining arguments made by consumer movement).

\textsuperscript{92} See Finnish Product Liability Act, supra note 55, § 7 (providing exceptions to liability but none for development risks). See also Hodges, supra note 17, at 296 (noting Finland excluded defense); Pearl, supra note 38, at 11 (observing Finland imposes liability for development risks).

\textsuperscript{93} See Hodges, supra note 17, at 474 (stating Consumer Protection Act prevented contractual excluding or limiting of liability); Taschner, note 36, at 26 (explaining Luxembourg law is same as French law and describing contractual liability under Article 1645 of sales law of Code).

\textsuperscript{94} See Hodges, supra note 17, at 474 (noting any seller must guarantee against defects which are not discoverable by due diligence); Howells, supra note 17, at 178
and anyone not in privity with the seller had to seek damages in tort. The Directive was implemented in Luxembourg through the Act of April 21, 1989 on Civil Liability for Defective Products. The development risk defense was excluded after some debate between the Judicial Commission of Luxembourg and the Luxembourg Chamber of Commerce. The Chamber of Commerce argued that the exclusion of the defense would put Luxembourg in a disadvantageous position for inter-EU trade, inhibit innovation and penalize industries that developed new products. The Luxembourg Parliament, fearful that the development risk defense would erode consumer protections, excluded the defense.

3. France

Prior to the passing of the European Directive, France was the leader in the movement towards strict liability for prod-

(explaining clauses limiting or excluding liability for hidden defects were made invalid by law).

95. See Hodges, supra note 17, at 475 (stating persons not in privity with producer may sue latter in tort); Michelle Fontaine & Thierry Bourgoignie, Consumer Legislation in Belgium and Luxembourg 210 (Michael Corkery trans., 1982) (noting Article 1982 imposes liability on sellers and third parties).

96. Luxembourg's Product Liability Act, supra note 55. See also Hodges, supra note 17, at 475 (noting implementing act and date on which legislation came into force); Pearl, supra note 38, at 11 (providing information on implementation of Directive in Luxembourg).


98. See Luxembourg's Proposed Law, supra note 97, at 9-10 (arguing imposition of liability for development risk disincetivizes innovation by penalizing producers of new products and puts Luxembourg at disadvantage for inter-EU trade). See also Linger, supra note 14, at 499 (stating excluding defense would put Luxembourg at trade disadvantage by isolating it from rest of Member States and discourage innovation of new products).

99. See Luxembourg's Proposed Law, supra note 97, at 4-5 (reporting Judicial Commission did not want to erode consumer protection); Linger, supra note 14, at 498 (explaining development risks defense was rejected because Judicial Commission feared it would erode consumer protection).

100. See Luxembourg's Product Liability Act, supra note 55, art. 4 (exempting producers from liability but not for development risks). See also Hodges, supra note 17, at 296 (noting Luxembourg excluded defense); Pearl, supra note 38, at 11 (observing Luxembourg imposes liability for development risks).
ucts. Exceeding even the early U.S. approach of *res ipsa loquitur*, the French *Cour de Cassation* established an irrebuttable presumption of manufacturer negligence. The effects of the presumption were muted by French tort law, however, which did not consider buyers to be proper plaintiffs. Tort actions could only be brought by non-purchasing third parties only; buyers were required to sue under contract theory. Under the Civil Code, warranty law applied to products cases and was in fact more generous to injured plaintiffs than the U.S. Uniform Commercial Code. Most notably, a lack of privity is not a bar in mass-marketing situations and plaintiffs were not limited to the price of replacement of the defective good for damages.

The development risk defense caused great controversy in

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101. See Freedman, *supra* note 29, at 16 (declaring movement towards strict liability was led by France); Howells, *supra* note 17, at 101 (pointing out among Member States, France had most protective product liability law prior to Directive).

102. See, e.g., Cass. Civ., July 22, 1931: [1931] II Gaz. Pal. 683 (holding that marketing of defective products is sufficient proof of manufacturer’s fault). See also Culhane, *supra* note 25, at 21 (remarking *Cour de Cassation* established irrebuttable presumption of manufacturer negligence); Hodges, *supra* note 17, at 323 (summarizing French High Court has consistently held for more than fifty years that mere marketing of defective products constitute proof of manufacturer fault).


104. See C. Civ., *supra* note 103, art. 1384 (providing action in tort). See also Culhane, *supra* note 25, at 21 (noting tort section only apply to nonpurchasing third parties); Albanese & Del Duca, *supra* note 40, at 199 (stating injured non-purchaser must act in tort).

105. See C. Civ., *supra* note 103, art. 1641 (establishing actions under warranty law). See Culhane, *supra* note 25, at 21 (remarking buyers had to sue under contract theory); Albanese & Del Duca, *supra* note 40, at 199 (explaining non-purchaser may sue in tort).

106. See C. Civ., *supra* note 103, art. 1641 (offering warranties against defective products).

107. See Culhane, *supra* note 25, at 22 (pointing out French Civil Code is more generous than U.S. Uniform Commercial Code to plaintiffs because lack of privity does not bar claims in mass-marketing situations and plaintiffs are not limited to purchase price of defective goods for damages).

108. See Culhane, *supra* note 25, at 22 (observing plaintiffs in mass-marketing situations have been permitted to proceed against manufacturer directly, in spite of lack of privity); Howells, *supra* note 17, at 106 (asserting French contract law overcomes privity of contract hurdle by allowing *actions directes* by sub-purchasers); Howells, *supra* note 17, at 103-04 (describing how French system allows plaintiff to receive consequential damages cause by product).
France and resulted in delays in the adoption of the Directive.\textsuperscript{109} On the one hand, allowing for a development risk defense was contrary to French jurisprudence, which held producers responsible for unknown defects, even if the producer was able to prove that the defect was not discoverable at the time the product was put into circulation.\textsuperscript{110} Commentators further argued that the defense would incentivize willful blindness on the part of manufacturers or cause manufacturers to adopt a code of silence regarding defective products, thereby undermining consumer protection.\textsuperscript{111} On the other hand, the Conseil National du Patronat Francais was concerned that a French exclusion of the defense, would undermine the Directive's objective of harmonization and would encourage forum shopping.\textsuperscript{112} Additionally, there was at least some precedent for a development risk defense, France having allowed the defense for pharmaceuticals.\textsuperscript{113} After much

\begin{quote}
\textsuperscript{109} See Hurd, \textit{supra} note 27, at 61 (noting debate over possible inclusion of development risk defense held up harmonization process); French failure to implement directive, \textit{supra} note 60 (stating French implementation of Directive had been stalled by disagreement over development risk defense).

\textsuperscript{110} See Linger, \textit{supra} note 14, at 501 (noting French jurisprudence provides that producer is responsible for unknown defects regardless of whether defect was discoverable at time product was put into circulation); Howells, \textit{supra} note 17, at 102 (discussing Article 1641 which made sellers liable for hidden defects and stating undisclosability of defect was not defense on general principles).

\textsuperscript{111} See Rothman & Finon, \textit{Responsabilité du fait des Produits: Vers le Développement d'un Régime Défectueux}, 124 \textit{Fiches Juridiques} 6 (1988) (Institute for Consumer Affairs, France, Pub. No. 610) (expressing concern that development risk defense will undermine consumer protection by providing incentive for manufacturers to be willfully blind or remain silent about defective products); Linger, \textit{supra} note 14, at 501-02 (citing commentators' concern that fear of liability will cause producers to adopt code of silence regarding defective products).


\textsuperscript{113} See Hurd, \textit{supra} note 27, at 61 (noting pre-Directive French law imposed liability for development risks with exception of pharmaceuticals); Anne E. Wells, \textit{Regulating Experimental AIDS Drugs: A Comparison of the United States and France}, 13 \textit{Loy. L.A. Int'l & Comp. L.J.} 393, 408 (1990) (citing 1973 decision where French court held that producer distributing product which carries risks but is only treatment available is not negligent).
\end{quote}
debate, France opted in on the development risk defense.\textsuperscript{114} The draft implementing act cited the chilling effect on research and development, and the disadvantageous position France would be in compared to European competitors if it were to opt out of the defense as reasons for France's acquiescence to the defense.\textsuperscript{115}

France finally incorporated the Directive into national law on May 19, 1998.\textsuperscript{116} Although France conceded to the development risk defense, the controversy surrounding the defense did not subside.\textsuperscript{117} Article 1386-12 of the French Civil Code provides that a producer must prove that he has taken the steps appropriate to avert the harmful consequences of a defective product in order to invoke the development risk defense.\textsuperscript{118}

\begin{itemize}
\item \textsuperscript{114} See French Product Liability Act, \textit{supra} note 61, art. 12 (implementing development risk defense). \textit{See also} Green Paper, \textit{supra} note 56, at 34 (reporting France ultimately allowed development risk defense with exception of products derived from human body); PEARL, \textit{supra} note 38, at 11 (stating France does not allow liability for development risks apart from products derived from human body).
\item \textsuperscript{115} See HODGES, \textit{supra} note 17, at 327 (discussing preamble of Draft Act as being concerned with impairment of research and development and European competition resulting from Member States, should development risk defense be excluded); Howells, \textit{supra} note 17, at 117 (stating French industry convinced government to include defense since France's major trading partners had almost unanimously opted in on defense).
\item \textsuperscript{117} \textit{See also} Opinion of Advocate General Geelhoed, \textit{French Republic}, [2001] E.C.R. \_\_\_ (representing debate between Commission and French Republic on how to apply development risk defense).
\item \textsuperscript{118} \textit{See} French Product Liability Act, \textit{supra} note 61, art. 13 (inserting Article 1386-12 into French Civil Code). Article 1386-12, ¶ 2 states:

\begin{quote}
Le producteur ne peut invoquer les causes d'exonération prévues aux 4\textsuperscript{e} et 5\textsuperscript{e} de l'article 1386-11 si, en présence d'un défaut qui s'est révélé dans un délai de dix ans après la mise en circulation du produit, il n'a pas pris les dispositions propres à en prévenir les conséquences dommageables [The producer cannot call upon the causes of exemption of article 1386-11 if, in the presence of a defect which appeared within ten years after putting into circulation of the product, it did not make the provisions suitable to prevent the detrimental consequences of them].
\end{quote}

\textit{Id.} \textit{See also} Opinion of Advocate General Geelhoed, \textit{French Republic}, [2001] E.C.R. \_\_\_ at ¶ 10 (asserting French Republic has failed to fulfill its obligations under Directive by providing that development risk defense applies only in cases where producer had taken appropriate steps to avert harmful consequences of defective product in Article 1386-12 of Civil Code).
mental risk defense, however, as defined by the Directive, is not a conditional defense. After the European Commission failed to resolve the issue through an exchange of letters with France's Permanent Representative, it brought action against the French Republic for failing to fulfill its obligation under the Directive and under the EC Treaty.

The French Government justified its actions on three grounds. It argued first that the European Commission is itself considering an amendment to exclude the development risk defense. Second, the Directive gives Member States a certain amount of flexibility in the implementation of the optional provision. Third, the obligation imposed by Article 1386-12 is explicitly laid down in another directive, the General Product

119. See European Report, supra note 116, at 2467 (stating French legislation did not comply with Directive because liability exemption for development risk was conditioned on preventive measures taken by producer). See also Opinion of Advocate General Geelhoed, French Republic, [2001] E.C.R. _ at ¶ 10 (asserting French Republic has failed to fulfill its obligations under Directive by providing that development risk defense applies only in cases where producer had taken appropriate steps to avert harmful consequences of defective product in Article 1386-12 of Civil Code).

120. See Opinion of Advocate General Geelhoed, French Republic, [2001] E.C.R. _. See generally, European Report, supra note 116, at 2467 (describing proceedings against France for failure to implement Directive). The responsibility of sanctioning for non-implementation of directives adopted by the EC fall to the European Court of Justice of the European Communities. See Hanlon, supra note 10, at 58 (stating Court prevents Member States from neglecting duties of implementation of legislation); Vincenzi & Fairhurst, supra note 10, at 127 (noting Court is responsible for ruling on validity and interpretation of acts of institutions, including directives). The European Court of Justice is a Community institution with purely judicial functions whose purpose is to ensure "that the law is observed in the interpretation and applications of the Treaties establishing the European Communities and of the provisions laid down by the competent Community institutions." Jurisdiction of the European Court of Justice, European Court of Justice website, available at http://europa.eu.int/cj/en/instit/presentationfr/index.htm. See also, Hanlon, supra note 10, at 57-58 (explaining role of European Court of Justice to be in ensuring effectiveness of Community law). In interpreting Community law, the European Court of Justice must carefully accommodate the background of differing legal systems of the Member States on the one hand, while supplementing Community law with national law when necessary on the other. See Freedman, supra note 29, at 3, 7; Vincenzi & Fairhurst, supra note 10, at 127 (noting EC Treaty envisioned partnership between European Court of Justice and national court).


122. See id. (arguing European Commission itself is considering amending development risk defense).

123. See id. (asserting Directive allows some freedom in implementation development risk defense).
Safety Directive,\textsuperscript{124} which imposed an obligation on producers to monitor products which are sold.\textsuperscript{125} In response, the European Commission stated that the development risk defense did not conflict with the General Product Safety Directive, which is concerned with the general obligations of producers to ensure the safety of their products.\textsuperscript{126} Furthermore, the European Commission noted that the action for failure to implement a provision cannot be decided on possible future amendments to the Directive.\textsuperscript{127} Advocate General ("AG") Geelhoed\textsuperscript{128} sided with the European Commission, stating that "a Member State's obligations under Community law must be determined by reference to the state of Community law on the date when the action was


\textsuperscript{125} See Opinion of Advocate General Geelhoed, French Republic, [2001] E.C.R. \_ at ¶ 83. The French Republic argued:

The French Government finds it incomprehensible that the exemption should not be subject to the obligation to monitor products which are sold, since that would be a logical complement to the safety principle. The French Government concludes that such an obligation is explicitly laid down in Directive 92/59 and that it also entails an obligation to ensure that products are traceable, an obligation to keep up to date with new scientific developments, and an obligation to inform those individuals who are exposed to them of new risks which have come to light.

\textit{Id.}

\textsuperscript{126} See id. at ¶ 84 (stating European Commission's rebuttal that General Product Safety Directive concerns general obligations regarding safety rather than imposing liability for defective products).

\textsuperscript{127} See id. (noting European Commission's rebuttal that actions for failure to fulfill obligations cannot be based on ongoing debates about future amendments).

\textsuperscript{128} See \textsc{Hanlon}, supra note 10, at 58 (observing European Court of Justice is made up of fifteen judges and nine Advocate Generals); \textsc{Vincenzi \& Fairhurst}, supra note 10, at 93 (remarking that fifteen judges and nine Advocate Generals make up European Court of Justice). The European Court of Justice consists of fifteen judges assisted by nine Advocates Generals. See id. One Advocate General ("AG") is assigned to each case. See \textsc{Hanlon}, supra note 10, at 59 (noting one AG is assigned to each case); \textsc{Vincenzi \& Fairhurst}, supra note 10, at 95-96 (stating each case will have one AG). The function of the AG is to issue a written opinion setting out the applicable law to the case and recommending to the European Court of Justice how the case ought to be decided. See \textsc{Hanlon}, supra note 10, at 59-60 (describing advisory role of AG in Court of Justice); \textsc{Vincenzi \& Fairhurst}, supra note 10, at 95-96 (discussing role of AG as outlining applicable law and recommending course of action to Court of Justice).
brought." As a result, the AG concluded that the French Republic failed to comply fully with the Directive. Pursuant to the AG's recommendation, the European Court of Justice ruled that France had failed to fulfill its obligations under the Directive. As of July 2003, France had yet to comply with the European Court of Justice's judgment of April 2002.

4. Spain

Spanish contract-based product liability allowed two distinct rights of action, under the law of sales and the obligations theory. The obligations theory, as described in Article 1101 of the Spanish Civil Code, made a seller liable for damages and harms caused through negligence. Article 1484 further held sellers

131. See Hanlon, supra note 10, at 60 (noting Court follows AG's opinion in majority of cases); Vincenzi & Fairhurst, supra note 10, at 96 (noting AG's opinion is followed by European Court in vast majority of cases). In the majority of cases, the European Court of Justice follows the opinion of the AG although the opinion is not binding. Id. In 1988, the European Court of First Instance was created to bring relief to an overburdened European Court of Justice. See Hanlon, supra, at 60 (discussing Court of First Instance); Vincenzi & Fairhurst, supra note 10, at 120 (mentioning creation of Court of First Instance).
133. See Internal Market (July 14, 2003), supra note 130, at 4 (stating European Commission will be sending France reasoned opinion given its failure to comply with European Court of Justice's 2002 judgment despite being sent letter of formal notice by European Commission); Internal Market (Apr. 28, 2003), supra note 130, at 1 (citing France's failure to comply with European Court of Justice's judgment of April 25, 2002).
134. See Ansaldi, supra note 54, at 378 (discussing two forms in which claim may be advanced through contract theory); Hodges, supra note 17, at 585-87 (explaining two aspects of contractual liability under Spanish law: civil law and special law of mercantile obligations).
135. See Código Civil art. 1101 (Sp.), translated in, Civil Code of Spain 274 (Julio Romanach, Jr. trans., 1994) [hereinafter C.C.] (stating "those who, in the performance
responsible for latent product defects regardless of whether sellers were aware of the defect; in other words, strictly liable.\textsuperscript{136} Under the obligations theory, sellers were liable for injuries foreseeable at the time the obligation arose, thereby excluding liability arising from development risks.\textsuperscript{137}

As with other countries, contract based claims were limited to those in privity.\textsuperscript{138} Those not in privity with the seller had to sue in tort.\textsuperscript{139} Article 1902, which outlines fault-based liability, provided a claim based on negligence.\textsuperscript{140} Similar to the French,\textsuperscript{141} the Spanish courts created a presumption of seller negligence,\textsuperscript{142} which in effect reversed the burden of proof forcing sellers to prove lack of fault.\textsuperscript{143} The Spanish took a more

of their obligations, incur . . . negligence . . . are liable for the resulting damages\textsuperscript{\textquotedblright}). \textit{See also} Ansaldi, \textit{supra} note 54, at 378-79 (describing obligations theory of contracts).

\textsuperscript{136} \textit{See} C.C., \textit{supra} note 135, art. 1484 (stating "the seller is obligated to give warranty for the hidden defects that the thing sold may have, if such defects render the thing unsuitable for the use to which it is destined"). \textit{See also} Ansaldi, \textit{supra} note 54, at 379 (explaining sellers are responsible for latent defects under law of sales); Hodges, \textit{supra} note 17, at 585 (citing Article 1484 as making seller liable for hidden defects in good being sold).

\textsuperscript{137} \textit{See} Ansaldi, \textit{supra} note 54, at 380 (noting foreseeability in obligations theory excludes liability from development risks); Gerd Bruggemann, \textit{Die Produkthaftung im Spanischen Recht} 91 (1988) (remarking producers are not liable for development risks under obligations theory because of foreseeability element required for liability).

\textsuperscript{138} \textit{See} C.C. art. 1257 (stipulating contractual obligations are between contracting parties and their heirs only). \textit{See also} Ansaldi, \textit{supra} note 54, at 381 (commenting privity requirement is obvious drawback to contract theory); Hodges, \textit{supra} note 17, at 586 (citing Article 1257 as forbidding third party damaged by defective product to sue producer directly).

\textsuperscript{139} \textit{See} Ansaldi, \textit{supra} note 54, at 381 (noting plaintiffs must recover under tort theory if not in privity of contract with their defendant); Hodges, \textit{supra} note 17, at 587 (outlining basis by which non-contractual liability may be imposed).

\textsuperscript{140} \textit{See} C.C. art. 1902 (providing cause of action for damages caused by fault or negligence). \textit{See also} Ansaldi, \textit{supra} note 54, at 381 (describing liability under tort law); Hodges, \textit{supra} note 17, at 587 (explaining Article 1902 requires existence of negligence for non-contractual liability).

\textsuperscript{141} \textit{See} Culhane, \textit{supra} note 25, at 21 (asserting Cour de Cassation established irrebuttable presumption of manufacturer negligence); Hodges, \textit{supra} note 17, at 323 (observing French High Court has held for more than fifty years that mere marketing of defective products constitute proof of manufacturer fault).

\textsuperscript{142} \textit{See, e.g.,} Judgment of the Supreme Court of June 22, 1931 (noting presumption of negligence in extra-contractual liability). \textit{See also} Ramon Mullerat & Sonia Cortes, \textit{Spain, in European Products Liability} 339, 348 (Patrick Kelly & Rebecca Attree eds., 1992) (reporting presumption of negligence by producer).

\textsuperscript{143} \textit{See} Ansaldi, \textit{supra} note 54, at 382 (noting Spanish courts inverted burden of proof, requiring defendant to prove diligence); Hodges, \textit{supra} note 17, at 588 (describing reversal in burden of proof in Spanish jurisprudence which requires defendant to prove lack of guilt).
pro-consumer stance by making the presumption rebuttable.\textsuperscript{144} The major event that spurred the review of consumer protection law and resulted in the passing of the General Law for the Defense of Consumers and Users ("GAC") was the "Toxic Oil Syndrome" of 1981 in which over four hundred people died or became seriously ill from ingesting reprocessed industrial rapeseed oil marketed for cooking and consumption.\textsuperscript{145} The GAC codified existing Spanish jurisprudence, like the rebuttable presumption of fault and set up a strict liability regime in Spain.\textsuperscript{146} Everyone in the production and distribution chain was held strictly liable.\textsuperscript{147} The GAC was severely criticized for sloppy draftsmanship but nevertheless signified a major advance for Spanish consumers.\textsuperscript{148}

It took Spain nine years and four drafts\textsuperscript{149} to implement the Directive in what is now the Spanish Products Liability Act of 1994 ("SPLA").\textsuperscript{150} The inclusion of the development risk de-

\textsuperscript{144} See Ansaldi, supra note 54, at 382 (stating presumption of producer fault was subject to rebuttal); Mullerat & Cortes, supra note 142, at 348 (observing rebuttable presumption of producer fault).

\textsuperscript{145} See Ansaldi, supra note 54, at 383 n.69 (describing incident where denatured industrial grade oil was sold for consumption). See also Howells, supra note 17, at 184 (discussing ‘Colza oil disaster where industrial grade oil was denatured and distributed as cooking oil); Richard Lorant, Mass Poisoning in Spain Still Slept in Mystery, L.A. Times, June 16, 1991, at A6 (commenting on Spanish rapeseed oil incident where denatured industrial grade oil was sold as cooking oil). Ansaldi asserts that the Los Alfaques disaster of 1978, in which a tanker carrying 23,000 kilos of liquid propylene gas crashed into a campsite wall exploding and killing 215 campers was also significant in forcing Spanish law makers to review consumer protection laws. See Ansaldi, supra note 54, at 383 n.69 (describing Los Alfaques disaster where tanker carrying propylene gas crashed and exploded killing 215 campers); Fay Willey, A Scene Out of Dante, Newsweek, July 24, 1978, at 53 (reporting on Los Alfaques disaster where hundreds were killed when tanker carrying propylene gas crashed and exploded).


\textsuperscript{147} See Ansaldi, supra note 54, at 388 (stating that liable parties included almost everyone in production and distribution chain); Howells, supra note 17, at 185 (discussing Article 27 providing for allocation of liability).

\textsuperscript{148} See Ansaldi, supra note 54, at 389 (criticizing sloppy draftsmanship of GAC); Hodges, supra note 17, at 589 (noting GAC is ambiguous and difficult to interpret when it comes to limits or exclusions of liability).

\textsuperscript{149} See Ansaldi, supra note 54, at 387-88 (noting first two drafts were prepared in 1988 and SPLA was finally promulgated in 1994); Domecq, supra note 146, at 158-59 (describing four drafts of SPLA).

\textsuperscript{150} Spanish Product Liability Act, supra note 54. See Ansaldi, supra note 54, at 375 n.18 (noting implementing act and date on which legislation came into force); Pearl,
defense was, of course, in contention.\textsuperscript{151} The limited acceptance of the development risk defense is believed to be due to the Thalidomide crisis that shook Europe and to the Toxic Oil Syndrome.\textsuperscript{152} In the end, Spain decided to allow a partial defense.\textsuperscript{153} The SPLA allows for a development risk defense\textsuperscript{154} except as to "pharmaceutical products, foodstuffs or food products intended for human consumption."\textsuperscript{155}

5. United Kingdom

In the United Kingdom, the duty to non-consumers was recognized when the rule of privity was abandoned by \textit{Donoghue v. Stevenson}.\textsuperscript{156} \textit{Donoghue} allowed a fault-based cause of action for

\begin{itemize}
  \item \textsuperscript{151} See Ansaldi, \textit{supra} note 54, at 397-98 (noting disagreements between Ministry of Justice, proposing to allow development risk defense except for pharmaceutical products, and Ministry of Health and Consumption, which wanted to exclude both medicines and food from defense); Domecq, \textit{supra} note 146, at 158-59 (stating Ministry of Justice sought to exclude development risk defense for pharmaceutical products while Ministry of Health and Consumption wanted to exclude development risk defense for both medicines and foods).
  \item \textsuperscript{152} See Ansaldi, \textit{supra} note 54, at 397 n.134, 406 n.165 (stating European Commission considered Germany's Pharmaceuticals Law in excluding defense for pharmaceuticals and attributing elimination of defense for food products to be due to Toxic Oil Syndrome). \textit{See generally}, I. Vega, \textit{The Defence of the Development Risks in Spanish Law}, 1997 CONSUMER L.J. 144 (discussing Spain's exclusion of development risks defense for high risk products).
  \item \textsuperscript{153} See Ansaldi, \textit{supra} note 54, at 400 (remarking pharmaceutical products and food products are excluded from development risk defense); Hodges, \textit{supra} note 17, at 591 (observing draft SPLA included defense, but not for pharmaceuticals or food products).
  \item \textsuperscript{154} See Spanish Product Liability Act, \textit{supra} note 54, art. 6(1)(e) (outlining development risk defense).
  \item \textsuperscript{155} See Spanish Products Liability Act, \textit{supra} note 54, art. 6(3) (stating exceptions to development risk defense). \textit{See also} Ansaldi, \textit{supra} note 54, at 428-29 (noting pharmaceutical products and food products are excluded from development risk defense); Hodges, \textit{supra} note 17, at 591 (noting draft SPLA included defense, but not for pharmaceuticals or food products).
\end{itemize}
injuries caused by defective products.\textsuperscript{157} Actions for negligence were not limited to those in privity to the defendant.\textsuperscript{158} Negligence-based product liability law in England developed into strict liability through legislative action with the Sale of Goods Act of 1979.\textsuperscript{159} Thus, starting from 1979, consumers had the option to bring an action under statutorily created warranties,\textsuperscript{160} and recovery was allowed for both physical and pure economic loss caused by breach of warranty.\textsuperscript{162} Contract claims however, remained limited to those in privity with the seller.\textsuperscript{163}

The United Kingdom implemented the Directive through the Consumer Protection Act, which came into force on March 1, 1988.\textsuperscript{164} The inclusion of the development risk defense in the Directive was largely the contribution of the Thatcher administration, which agreed to sign the Directive only after the provision was included in the final version of the Directive.\textsuperscript{165}

\footnotesize{157. See Awad, supra note 156, at 284 (stating Donoghue created negligence cause of action for defective products); Stapleton, \textit{Myths of Reform}, supra note 13, at 50 (discussing tort of negligence and duty imposed on those engaged in commercial manufacture and supply of goods and services).

158. See Stapleton, \textit{Myths of Reform}, supra note 13, at 50 (reporting negligence claims were not limited by privity); HODGES, supra note 17, at 663 (asserting duty of care extended to every person in chain of design, manufacture and supply).


160. See Stapleton, \textit{Myths of Reform}, supra note 13, at 48 (pointing out obligations imposed by Act include statutory warranty as to quality and fitness for purpose); HODGES, supra note 17, at 660 (citing Section 14 of Sale of Goods Act).

161. See Stapleton, \textit{Myths of Reform}, supra note 13, at 49 (noting warranties were implied in contract of sale by law); HODGES, supra note 17, at 660 (stating "merchantable quality" and "fitness for purpose" were implied terms in Sale of Goods Act).

162. See Stapleton, \textit{Myths of Reform}, supra note 13, at 49 (reporting recovery is allowed for pure economic loss); KELLY & ATTREE, supra note 17, at 444 (remarking economic loss not related to physical or property damage are recoverable).

163. See Stapleton, \textit{Myths of Reform}, supra note 13, at 49 (explaining only parties who sold defective product can be sued and only buyers can sue); HODGES, supra note 17, at 661 (noting that seller is liable for defective product even if he has exercised all reasonable care and may not restrict his liability against consumer).

164. See Consumer Protection Act, supra note 53 (incorporating Directive into UK national law). See PEARL, supra note 38, at 11 (providing date of adoption of UK's national product liability law); HODGES, supra note 17, at 669 (reporting implementing act and date on which legislation came into force).

165. See Stapleton, \textit{Myths of Reform}, supra note 13, at 56-57 (stating Thatcher administration specifically demanded inclusion of development risk defense and agreed}
the exception of the United Kingdom, all Member States adopted the development risk defense verbatim from the wording in the Directive. The drafters of the Consumer Protection Act chose to deviate from the wording of the Directive when it came to the development risk defense, wording the defense in a manner that gave it producer-friendly construction. Because of this qualification, the European Commission brought an action against the United Kingdom for failing to fulfill its obligation under the Directive and under the EC Treaty.

II. DEVELOPMENT RISK DEFENSE AND STATE-OF-THE-ART

Most commentators recognize that the Directive was inspired by Section 402A of the American Law Institute's Restatement (Second) of Torts ("Restatement (Second)"). The controver-


169. See Price, supra note 51, at 1338 (noting Directive mirrors Section 402A of Restatement (Second)); Henderson & Twerski, supra note 17, at 11 (criticizing Europe for committing itself to same position as that of Section 402A of Restatement (Second)). Section §402A states:
sies surrounding Section 402A, specifically in defining "design defect," reflect the tension between strict liability and negligence concepts. The EC, having based the Directive on Section 402A did not escape this debate. Commentators argue that absolving manufacturers of liability associated with unknowable or unavoidable risks muddles a strict liability system with exceptions. Others argue that it is inherently unfair to hold manufacturers liable for risks over which they have no control. The tension between strict liability and negligence regimes is highlighted by the controversy surrounding the state-of-the-art defense in the United States and the development risk defense in Europe.

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

Id.
A. Development Risk Defense and State-of-the-art Concept Distinguished

The development risk defense provides that a producer will not be held liable for a defective product if he proves that at the time he put his product into circulation, the existence of the defect was undiscoverable given the state of scientific and technical knowledge.\textsuperscript{175} There has been some confusion as to the scope of development risk and whether there is any overlap with state-of-the-art, as it is used in U.S. product liability law.\textsuperscript{176} One commentator used state-of-the-art and "development risks" synonymously, stating that discovery of the defect in a product must have been absolutely impossible for the defense to apply.\textsuperscript{177} This conflation of state-of-the-art with "development risks," oversimplifies the relevant concepts.\textsuperscript{178} State-of-the-art, as it is used in U.S. product liability law, can mean anything from industry custom to technological feasibility.\textsuperscript{179} "Development risk" in the EC has been defined more narrowly.\textsuperscript{180} Another commentator

\textsuperscript{175}. See Directive, supra note 11, art. 7(e) (establishing development risk defense).
\textsuperscript{176}. See, e.g., Linger, supra note 14, at 488 (stating "Article 7(e) defines 'state of the art' or development risks defense"); Taschner, supra note 36, at 31-32 (distinguishing between state-of-the-art concept and development risk concept). For the purposes of this Note, "state-of-the-art" will refer to the U.S. consideration of scientific and technology knowledge while "development risks" will refer to the defense as described in Article 7(e) of the Directive.
\textsuperscript{177}. See Linger, supra note 14, at 488 (using "state-of-the-art" and "development risks defense" synonymously).
\textsuperscript{179}. See Vandall, supra note 178, at 1200-03 (discussing various usages of state-of-the-art); Spradley, supra note 170, at 344-47 (summarizing common usages of state-of-the-art); Robb, supra note 170, at 4-5 (noting many different definitions of state-of-the-art).
\textsuperscript{180}. See Opinion of Advocate General Tesauro, United Kingdom, [1997] E.C.R. at ¶¶ 21-24 (holding liability depends on most advanced state of scientific knowledge and accessibility of that knowledge). See also Pearl, supra note 38, at 20 (summarizing holding of European Court of Justice in United Kingdom). In an article describing efforts to harmonize product liability law in the EC, Sandra Hurd writes:

[w]hile it is true that the Directive on Product Liability does not and never will effectuate complete harmonization, the variations among the Member States' harmonizing legislation and existing national laws are not significant enough
distinguished the two concepts by framing the state-of-the-art question as whether technical standards at the time a product was manufactured was followed, making the product non-defective even if it did cause damage, and the "development risk" defense as a defense against liability because the necessary scientific and technical knowledge did not exist at the time.181 Still others label the Article 6(1)(c) consideration of the time the product was put into circulation182 and the Article 6(2) subsequent remedial measures caveat183 as state-of-the-art, while "development risks" is treated as unknowable risks.184

B. State-of-the-art: The Path to Strict Liability and Back

1. Lessons from the Restatement (Second)

Section 402A of the Restatement (Second) is the most cited provision of the Restatement (Second).185 Following its publication in 1964, 402A has been adopted by a majority of jurisdictions.186

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181. See Taschner, supra note 36, at 31-32 (differentiating between state-of-the-art concept and development risk concept). According to Taschner, the Directive does not answer the state-of-the-art question and provides a defense for development risk only. See id. at 31 (stating "[t]he Directive does not provide for a 'state-of-the-art' defense").

182. See Directive, supra note 11, art. 6(1)(c) (stating "the safety which a person is entitled to expect taking all circumstances into account, including: (c) the time when the product was put into circulation").

183. See Directive, supra note 24, art. 6(2) (providing "[a] product shall not be considered defective for the sole reason that a better product is subsequently put into circulation").

184. See Shapo, supra note 174, at 301-02 (framing Articles 6(1)(c) and 6(2) provisions of Directive as state-of-the-art and describing development risks as risks unknowable at time of marketing). See also Thomas Lundmark, The Restatement of Torts (Third) and the European Product Liability Directive, 5 D.C.L. J. INT'L L. & PRAC. 259, 256 (1996) (stating that cases presenting issues of unknowable risks outline scope of development risk defense).


The correct interpretation of 402A has been more controversial, however, especially in the evaluating of product defects.\textsuperscript{187} The jurisprudence of 402A has identified three broad categories of product defect: design defect, manufacturing defect, and warning defect.\textsuperscript{188} Courts and commentators have noted that determining the proper test for design defectiveness has dominated product liability law over the last four decades.\textsuperscript{189}

\textbf{a. Design Defectiveness}

Section 402A is silent when it comes to defining design defectiveness,\textsuperscript{190} but \textit{comment i} suggests that 402A applies when the product defect makes it "unreasonably" dangerous to the consumer.\textsuperscript{191} Relying on the reference to the consumer as the judge of defectiveness in \textit{comment i}, courts devised the "consumer expectation test" to evaluate design defectiveness.\textsuperscript{192} The expectation of the ordinary consumer, a concept that focuses strictly on the product and not on the conduct of the manufacturer is the focus.\textsuperscript{193} Over the years, courts have formulated other ap-


\textsuperscript{190} See Kysar, \textit{supra} note 189, at 1711 (pointing out Section 402A does not define defectiveness); Joseph W. Little, \textit{The Place of Consumer Expectations in Product Strict Liability Actions for Defectively Designed Products}, 61 Tenn. L. Rev. 1189, 1993 (1994) (stating Section 402A does not define design defect).

\textsuperscript{191} See \textit{Restatement (Second)} \S 402A, cmt. i (1965).

\textsuperscript{192} See Kysar, \textit{supra} note 189, at 1719-13 (discussing \textit{comment i} and consumer expectation test); Jankowski, \textit{supra} note 187 at 314-18 (outlining consumer expectation approach).

\textsuperscript{193} See Henderson & Twerski, \textit{supra} note 7, at 492 (observing some commentators and courts denounce risk-utility test which sounds very much like negligence and
approaches to determining the adequacy of product design, most notably the risk-utility test. The risk-utility test determines the reasonableness of the manufacturer's design decision in balancing the potential risks involved and the cost to the manufacturer of preventing injuries, a concept very much rooted in negligence theory.

b. Defining State-of-the-art

Highlighting the tension between negligence-based product liability and strict product liability was the issue of admissibility of state-of-the-art evidence. Cases where state-of-the-art evidence becomes an issue involve mostly design defect issues since the determination of design defectiveness is highly dependant on scientific and technological advances. First used in a 1956 Illinois case involving an allegedly negligently designed door, state-of-the-art was never clearly defined, leading to the present advocate test based on consumer expectations). See also Green v. Smith & Nephew AHP, Inc., 629 N.W.2d 727, 802 (2001) (holding Wisconsin strict product liability law only applies consumer expectation test and that focus is on nature of defendant's product rather than on defendant's conduct).

194. See Kysar, supra note 189, at 1711-12 (explaining that risk-utility analysis considers potential risks of injury and costs to manufactures to prevent injuries); Jankowski, supra note 187 at 318-24 (detailing risk-utility approach as balancing test which considers risks of injury and cost to prevent injuries).

195. See John W. Wade, On the Nature of Strict Tort Liability for Products, 44 Miss. L.J. 825 (1973) (proposing seven factors to be balanced in determining design reasonableness); Jankowski, supra note 187, at 295-96 (reporting risk-utility analysis compares advantages and disadvantages of potential designs).


197. See Spradley, supra note 170, at 348 (commenting on tension between negligence and strict liability theory and role of state-of-the-art); Robb, supra note 170, at 10 (characterizing relationship between state-of-the-art evidence and strict liability); Wertheimer, supra note 170, at 1206 (describing role of state-of-the-art in differentiating negligence based liability from strict product liability).

198. See Wade, supra note 188, at 740 (noting most problems involving time element have come from design cases since scientific developments tend to impact design defectiveness). See generally Henderson & Twerski, supra note 7, at 588 (discussing time dimensions of product design liability).

199. See Day v. Barber-Coleman Company, 135 N.E.2d 231, 237 (1956) ( remarking that "state-of-the-art" at time door was circulated would not have required material change in design). See also Robb, supra note 170, at 3 (crediting Day v. Barber-Colman for coining "state-of-the-art").
confusion over its precise meaning.\textsuperscript{200}

At least three discrete uses of the term state-of-the-art have appeared since its introduction in the mid-50's: (1) as customary industry practices;\textsuperscript{201} (2) as governmental standards;\textsuperscript{202} and (3) as the practicality or feasibility of a design.\textsuperscript{203} A fifty-state survey of the admissibility of state-of-the-art evidence is beyond the scope of this Note.\textsuperscript{204} The treatment of state-of-the-art evidence by a few selected states, however, is instructive.

Very few states hold state-of-the-art to be synonymous with industry practice, although even courts applying other standards have treated it as one factor to state-of-the-art determinations.\textsuperscript{205}

\begin{itemize}
\item \textsuperscript{200} See Robb, \textit{supra} note 170, at 5 (noting confusion that exists among courts in applying state-of-the-art concept); Vandall, \textit{supra} note 178, at 1193 (remarking there is no widely accepted definition of state-of-the-art).
\item \textsuperscript{201} See Vandall, \textit{supra} note 178, at 1193, 1200-03 (discussing various usages of state-of-the-art); Spradley, \textit{supra} note 170, at 344-47 (summarizing common use of state-of-the-art); Robb, \textit{supra} note 170, at 4-5 (noting many different definitions of state-of-the-art).
\item \textsuperscript{202} See Wertheimer, \textit{supra} note 170, at 1234 (discussing Supreme Court of Texas' holding in Boatland of Houston, Inc. v. Bailey, 609 S.W.2d 743 (Tex. 1980)); Spradley, \textit{supra} note 170, at 355-63 (raising argument against admitting state-of-the-art evidence when it is defined as industry practice); Robb, \textit{supra} note 170, at 16 (noting few courts treat state-of-the-art as industry standards).
\item \textsuperscript{203} See Vandall, \textit{supra} note 178, at 1200-01 (discussing use of government standards as state-of-the-art); Spradley, \textit{supra} note 170, at 367-74 (describing use of state-of-the-art evidence when it is defined in terms of governmental standards). The use of government standards as state-of-the-art evidence is more appropriately discussed under the federal preemption doctrine and will not be explored in detail in this Note. Generally, compliance with governmental regulations is indicative of a minimum effort required to make a product safe and does not serve as a defense. See Vandall, \textit{supra} note 178, at 1200-01 (discussing Wilson v. Piper Aircraft Corp., 577 P.2d 1322 (1978)); Spradley, \textit{supra} note 170, at 367 (stating governmental standards define minimum product design quality and conditions of distribution).
\item \textsuperscript{204} See Vandall, \textit{supra} note 178, at 1201-03 (discussing role of state-of-the-art in proving reasonable alternative design); Robb, \textit{supra} note 170, at 17-18 (pointing out use of state-of-the-art to set up parameters of feasibility).
\item \textsuperscript{205} Several useful compilations have been assembled by others. See generally Vargo, \textit{supra} note 186 (providing fifty state survey on design defect cases including treatment of state-of-the-art evidence); \textit{The State of the Art Defense in Product Liability Cases: A Fifty-State Survey} (James H. Rotondo ed., 1995) (outlining information on possible defenses to product liability in each state); \textit{Products Liability Defenses: A State-by-State Compendium} (Davidson Ream ed., 2001) (1992) (giving information on possible defenses to product liability in each state).
\item \textsuperscript{206} See Spradley, \textit{supra} note 170, at 359 (noting courts have considered industry practice probative in determining existence of design defect); James Boyd & Daniel E. Ingeberman, \textit{Should "Relative Safety" Be a Test of Product Liability?}, 26 J. Legal Stud. 433, 439-40 (1997) (observing adherence may be used to demonstrate that product's characteristics are consistent with consumer expectations).
\end{itemize}
Alaska and Texas have taken this minority position of treating industry practice as state-of-the-art evidence.\textsuperscript{207} The Supreme Court of Alaska discussed state-of-the-art and industry custom in Keogh v. W.R. Grasle, Inc.\textsuperscript{208} as if they were the same, noting that “state-of-the-art or industry custom evidence”\textsuperscript{209} was not dispositive in determining whether there is any liability but that the jury was allowed to consider such evidence.\textsuperscript{210} Additionally, the Supreme Court of Texas’ opinion in Bailey v. Boatland of Houston, Inc.\textsuperscript{211} is frequently cited on the question of whether industry standards should be admitted as state-of-the-art evidence.\textsuperscript{212} Samuel Bailey was thrown out of the boat he was operating and killed by the propeller when the boat circled back towards him.\textsuperscript{213} Samuel Bailey’s family sued the boat manufacturer for defectively designing the boat without a kill switch, which would have automatically shut down the motor of the boat when Bailey was thrown off.\textsuperscript{214} The defendant introduced evidence that the use of kill switches were known, but not used in the industry.\textsuperscript{215} Although the majority opinion in Boatland distinguished indus-

\textsuperscript{207} See e.g., Keogh v. W.R. Grasle, Inc., 816 P.2d 1343 (Alaska 1991) (discussing state-of-the-art and industry custom as if they were synonymous); Boatland of Houston, Inc. v. Bailey, 609 S.W.2d 743 (Tex. 1980) (allowing Defendant to escape liability because they followed industry custom).

\textsuperscript{208} 816 P.2d 1343 (Alaska 1991) (discussing state-of-the-art and industry custom).

\textsuperscript{209} Id. at 1349 (indicating Court’s synonymous treatment of the two concepts).

\textsuperscript{210} See id. The Court stated that:

Although the parties dispute whether industry custom and state of the art are distinct concepts, we find it unnecessary to resolve this question for the purposes of this appeal. We conclude that the fundamental evidentiary analysis ... should be identical regardless whether the evidence at issue here is considered industry custom or state of the art evidence.

\textit{Id.} at 1349 n.10. However, in \textit{Sturm, Ruger \& Co. v. Day}, the Court had stated that “[g]enerally speaking, ‘state of the art’ refers to customary practice in industry.” 594 P.2d 38, 44 (Alaska 1979).

\textsuperscript{211} 609 S.W.2d 743 (Tex. 1980) (allowing Defendant to escape liability by showing that they followed industry custom).

\textsuperscript{212} See Wertheimer, supra note 170, at 1234 (stating that state-of-the-art becomes state of industry custom in \textit{Boatland}); Vargo, supra note 186, at 908-11 (noting court allowed evidence of industry custom to rebut plaintiff’s claim of technological feasibility).

\textsuperscript{213} See \textit{Boatland}, 609 S.W.2d at 745 (reporting Bailey was thrown out of his boat and killed by propeller when boat circled back towards him).

\textsuperscript{214} See id. (explaining Bailey’s wife and children sued Boatland for not including kill switch, which they claim makes boat defectively designed).

\textsuperscript{215} See id. at 747 (noting Boatland introduced evidence that kill switches were not used in industry).
try custom from state-of-the-art textually, Justice Campbell argued in a dissenting opinion that practically speaking, the majority made no such distinction. Justice Campbell noted that the majority's decision was based on commercial unavailability of the kill switch, i.e., "the result of practice in the bass boat manufacturing industry" rather than "true limitation on feasibility to the manufacturer."

The most convincing argument against allowing consideration of industry standards is attributed to Judge Learned Hand in The T.J. Hooper. An entire industry may be negligent in failing to implement new technology but the "[c]ourts must in the end say what is required; there are precautions so imperative that even their universal disregard will not excuse their omission." As suggested by one commentator, admitting industry custom as state-of-the-art evidence would eviscerate the incentive for manufacturers to adopt safer practices.

Most courts differentiate between industry custom and state-of-the-art evidence, defining state-of-the-art as some variation of scientific or technological feasibility. Generally speaking, state-of-the-art refers to the reasonableness of a design considering the level of scientific and technical knowledge within eco-

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216. See id. at 748 (stating that custom is distinguishable from state-of-the-art).
217. See id. at 752 (emphasizing that state-of-the-art is not state of industry).
218. Id. See Wertheimer, supra note 170, at 1234 (remarking that state-of-the-art was equated to state of industry custom rather than state of technology). But see Vargo, supra note 186, at 910 (stating that Court distinguished custom from state-of-the-art).
219. 60 F.2d 737 (2d Cir. 1932) (holding that following industry custom does not exempt defendant from liability).
220. T.J. Hooper, 60 F.2d at 740. See Spradley, supra note 170, at 360-61 (quoting T.J. Hooper to argue against admitting industry custom as state-of-the-art); Boyd & Ingeberman, supra note 206, at 445 (discussing role of T.J. Hooper in admitting evidence of customary practice).
221. See Spradley, supra note 170, at 361 (noting that if standard of care is based on custom, one major purpose of imposing strict liability, providing an incentive for safer products, would be eviscerated); Lavelle, supra note 196, at 1071-72 (noting use of industry custom as state-of-the-art has been dismissed by courts as improper).
222. See Madden & Owen On Product Liability ch. 10, § 10:5, 631 (2003) [hereinafter Madden & Owen] (defining state-of-the-art as lying somewhere between industry custom and best science and technology in existence). For example, a Nebraska statute § 25-21,182 defines state-of-the-art as "the best technology reasonably available at the time" (Neb. Rev. St. § 25-21,182) while Arizona defines the term as "the technical, mechanical and scientific knowledge of manufacturing, designing, testing or labeling the same or similar products which was in existence and reasonably feasible for use at the time of manufacture" (Ariz. Rev. Stat. Ann. § 12-681(8)).
nomically practical bounds. While some jurisdictions allow defendants to submit state-of-the-art evidence as an affirmative defense to liability, other jurisdictions grant a rebuttable presumption in favor of non-defectiveness. The majority position is that state-of-the-art evidence is relevant to issues of product defectiveness, especially towards the determination of a reasonable alternative design.

c. Unknown or Unavoidable

In predicting the death of strict product liability in the United States, Professor Ellen Wertheimer lamented that by abolishing strict liability, courts have forgotten they are forcing an innocent plaintiff to bear the cost of the damage caused by the defective product, rather than the manufacturer who profited and was responsible for placing the defective product on the market in the first place. The battle between strict liability and negligence regimes reflects a debate over the apportionment of risk. Fact patterns which deal with unknown or una-


225. See, e.g., Colo. Rev. Stat § 13-21-403(1)(a); Ind. Code § 34-20-5-1; Ky. Rev. Stat. Ann. § 411.310(2). See generally Madden & Owen, supra note 222, at § 10.5 n.48-50 (discussing state statutes that create rebuttable presumptions). But note that the Illinois statute which created a rebuttable presumption of nondefectiveness (735 Ill. Comp. Stat. Ann 5/2-2104) was held unconstitutional by the Illinois Supreme Court in Best v. Talyor Machine Works, 689 N.E.2d 1057 (Ill. 1997) (holding that cap on compensatory damages for noneconomic injuries and provision deeming personal injury plaintiff to have consented to unlimited disclosure of all medical records were unconstitutional and invalid provisions were not severable from the remainder of the Civil Justice Reform Act of 1995).

226. See Wertheimer, supra note 170, at 1200 (noting state-of-the-art defense "entered through the balancing door" with requirement to show alternative feasible design); Spradley, supra note 170, at 416-33 (discussing feasibility of design changes).

227. See Wertheimer, supra note 170, at 1271 (commenting on unfairness of strict liability to plaintiff).

voidable risks\textsuperscript{229} are doctrinally critical to this debate because liability for such risks goes directly to the question of who should bear the loss associated with risks that do not implicate fault.\textsuperscript{230} It follows that the admissibility of state-of-the-art evidence plays an important role in the strict liability/negligence debate since it reflects the limits of scientific or technological knowledge,\textsuperscript{231} and is therefore directly relevant to whether a risk was unknown or unavoidable.\textsuperscript{232}

The discussion of unavoidable risks implicates comment \textit{k} of Section 402A,\textsuperscript{233} which has been referred to by some as the unavoidably unsafe product liability defense.\textsuperscript{234} Comment \textit{k} has effectively placed liability for unavoidable risks into the negligence regime by allowing defendants to escape liability as long as they warn of foreseeable dangers.\textsuperscript{235} The majority of jurisdictions have decided to follow comment \textit{k} for unavoidably unsafe prod-

\textsuperscript{229} As defined in this Note, unknowable risks involve risks that are either unforeseeable or undiscoverable prior to the design of the product while unavoidable are those that were known, but could not be prevented.

\textsuperscript{230} See Jane Stapleton, \textit{International Torts: A Comparative Study: Restatement (Third) of Torts: Products Liability, an Anglo-Australian Perspective}, 39 \textit{Washburn L.J.} 363, 368 (2000) [hereinafter Stapleton, \textit{International Torts}] (remarking on importance of fact situations related to undiscoverable product flaws for determining whether legal rule is one of strict liability); Owen, supra note 186, at 718 (criticizing strict liability for being unable to distinguish between reasonable conduct of manufacturers, whose product defect is undiscoverable prior to market, and bad conduct, for which manufacturer should be held liable).


\textsuperscript{232} See Spradley, supra note 170, at 379-411 (explaining unavoidable risks as undiscoverable risks and technological impossibility); Wertheimer, supra note 170, at 1210-12 (discussing unavoidable risks as absence of knowledge of cure and unknowable risks as absence of knowledge of product’s danger).

\textsuperscript{233} \textit{Restatement (Second) \S 402A, cmt. k} (1965). Comment \textit{k} states that “a product, properly prepared, and accompanied by proper directions and warning, is not defective.” \textit{Id.}

\textsuperscript{234} See Boyd & Ingeberman, supra note 206, at 438 (referring to comment \textit{k} as unavoidably unsafe product defense); Kysar, supra note 189, at 1721 n.92 (alluding to unavoidable unsafe product defense of comment \textit{k}).

The question that remained was whether liability should be imposed for products found to be defective because of unknowable risks.\textsuperscript{237}

d. Policy Considerations Related to State-of-the-art

Advocates of a strict liability system believe that strict liability ought to be genuinely strict rather than a higher form of negligence.\textsuperscript{238} They emphasize that the basic premise of imposition of liability without fault is to relieve plaintiffs of the burden of proving negligence.\textsuperscript{239} As Justice Traynor argued in \textit{Escola v. Coca Cola Bottling Co. of Fresno},\textsuperscript{240} the manufacturer is in the better position to identify the cause of the defect.\textsuperscript{241} One common argument against admitting state-of-the-art evidence is that such evidence goes to the reasonableness of the manufacturer's conduct; a consideration irrelevant to a strict liability system.\textsuperscript{242} From a policy perspective, commentators have argued that strict liability will minimize future accidents and distribute the cost of compensating plaintiffs throughout society.\textsuperscript{243} Accident minimization is achieved through deterrence, by motivating manufac-

\textsuperscript{236} See Walker, supra note 2, at 780 (citing comment k of Section 402A of Restatement (Second) for proposition that manufacturers are not liable for unavoidably safe products); Henderson & Twerski, supra note 7, at 456 (explaining comment k has been adopted in overwhelming majority of jurisdictions and imposes liability on drug manufacturers only if it fails to warn of defect).


\textsuperscript{238} See Spradley, supra note 170, at 420 (characterizing position of some courts as desiring genuinely strict liability system); Price, supra note 51, at 1279 (declaring that strict liability has been distorted beyond recognition by negligence concepts).

\textsuperscript{239} See Vargo, supra note 186, at 508 (asserting basic policy foundation for strict liability is to relieve consumer from burden of proving negligence); Ausness, supra note 237, at 742-44 (explaining burden of proof rationale for strict liability).

\textsuperscript{240} 150 P.2d 436 (Cal. 1944).

\textsuperscript{241} See Escola v. Coca Cola Bottling Co. of Fresno, 150 P.2d 436, 463 (Cal. 1944) (observing manufacturer is familiar with manufacturing process and is in better position than plaintiff to identify cause of defect); Vargo, supra note 186, at 508 (noting complexities of product make it difficult for plaintiff to establish defect compared to manufacturer who has access to expertise and information).

\textsuperscript{242} See id. at 389-90 (noting lack of fault is irrelevant since manufacturer's lack of knowledge of defect does not change fact that product was defective); Robb, supra note 170, at 14 (stating liability is imposed irrespective of reasonableness of manufacturer's conduct and solely on basis of defective product).

\textsuperscript{243} See Spradley, supra note 170, at 408 (discussing loss spreading and accident
turers to proceed with more care in identifying and correcting preventable risks and incentivizing them by encouraging research and development of newer and safer products.\textsuperscript{244} Loss spreading is achieved through insurance from a pool supported by the premiums of other manufacturers or passed on to consumers by raising the price of the product.\textsuperscript{245}

Very few courts have been adamant about not allowing state-of-the-art evidence.\textsuperscript{246} Wisconsin stands lonely, if not alone, in its refusal to consider state-of-the-art.\textsuperscript{247} The admissibility of state-of-the-art evidence in Wisconsin was decided in \textit{Green v. Smith & Nephew AHP, Inc.}\textsuperscript{248} Linda Green, a hospital worker who developed latex allergy from the gloves she was required to wear, sued Smith & Nephew AHP, Inc. ("S & N"), the manufacturer of the latex gloves.\textsuperscript{249} Green argued that the gloves were defectively designed because they contained excessive levels of allergy-causing latex proteins.\textsuperscript{250} Green also asserted that the cornstarch used to powder the gloves increased the possibility minimization as rationales for imposing strict liability); Wertheimer, supra note 170, at 1185-91 (describing economic reasons for imposing strict liability).

\textsuperscript{244} See Spradley, supra note 170, at 409 (explaining accident minimization rationale); Boyd & Ingeberman, supra note 206, at 470-71 (arguing if state-of-the-art is customary practice, manufacturers are unlikely to improve safety whereas if state-of-the-art is technological advancement, an incentive is provided for manufacturers to spend more on safety).

\textsuperscript{245} See Spradley, supra note 170, at 408 (discussing loss spreading rationale); Wertheimer, supra note 170, at 1187-89 (discussing cost spreading rationale).

\textsuperscript{246} See generally Vargo, supra note 186 (providing fifty state survey on design defect cases including treatment of state-of-the-art evidence); \textit{The State of the Art Defense}, supra note 205 (outlining information on possible defenses to product liability in each state); \textit{Products Liability Defenses}, supra note 205 (giving information on possible defenses to product liability in each state).

\textsuperscript{247} See Green v. Smith & Nephew AHP, Inc., 629 N.W.2d 727, 755-36 (Wis. 2001) (holding manufacturer responsible for injuries caused by products regardless of whether he had or could have had knowledge of potential danger).

\textsuperscript{248} 629 N.W.2d 727 (Wis. 2001) (declining to admit state-of-the-art evidence, holding it irrelevant in consumer expectation test).

\textsuperscript{249} See id. at 732 (reporting Green developed allergies to latex from gloves she was required to wear as hospital worker). See also Victor E. Schwartz & Rochelle M. Tedesco, \textit{The Re-emergence of "Super Strict" Liability: Slaying the Dragon Again}, 71 U. CIN. L. REV. 917, 918-19 (2003) (commenting on health care worker's product liability suit against manufacturer of latex gloves).

\textsuperscript{250} See Green, 629 N.W.2d at 732 (arguing design defect because of excessive levels of latex protein). See also Schwartz & Tedesco, supra note 249, at 919 (observing Green's lawyer argued that Smith & Nephew AHP, Inc. ("S & N") should have reduced level of latex protein).
that she would inhale the latex proteins.\textsuperscript{251} At the time Green started experiencing allergic reactions to the latex, the health care community was generally unaware that individuals could develop allergic reactions to latex proteins.\textsuperscript{252} The jury nevertheless returned a verdict in favor of the plaintiff after receiving instructions to use the consumer expectation test to determine design defectiveness.\textsuperscript{253} As part of the jury instruction, Milwaukee County Circuit Court reiterated that a manufacturer will be held liable for a defective and unreasonably dangerous product, regardless of whether the manufacturer had knowledge or could have known of the risk of harm.\textsuperscript{254} The defendant, S & N appealed, arguing that imposing liability for unknown defects transformed strict liability to absolute liability.\textsuperscript{255} To avoid absolute liability, an element of foreseeability must be included in product liability law.\textsuperscript{256} The Supreme Court of Wisconsin affirmed both the Milwaukee County Circuit Court and the Wisconsin Court of Appeals' decision to enter judgment on the jury's verdict, stating that foreseeability is an element of negligence, not strict liability, which only looks at the nature of the defendant's product.\textsuperscript{257}

Some courts import a notion of reasonableness into strict liability fearing that the pure form of strict liability, considering

\textsuperscript{251} See Green, 629 N.W.2d at 732 (asserting defectiveness in design due to use of corn starch in powder gloves, increasing likelihood of latex protein inhalation). See also Schwartz & Tedesco, supra note 249, at 919 (remarking Green's lawyer assert that gloves should not be made with cornstarch).

\textsuperscript{252} See Green, 629 N.W.2d at 733 (pointing out health care community did not know allergic reactions to latex would develop). See also Schwartz & Tedesco, supra note 249, at 919 (explaining that health care community was unaware that individuals could develop allergies from latex).

\textsuperscript{253} See Green, 629 N.W.2d at 736 (finding S & N's gloves defective and unreasonably dangerous after considering instructions to use consumer expectation test). See also Schwartz & Tedesco, supra, note 249, at 918 (describing Wisconsin's stubbornness in sticking to consumer expectation test in context of Green case).

\textsuperscript{254} See Green, 629 N.W.2d at 735-36 (declaring manufacturer liable for defective product even if manufacturer had no knowledge or could not have known of risk of harm of defect).

\textsuperscript{255} See id. at 744 (arguing that holding manufacturers responsible for defects that they do not and cannot know of transforms strict liability into absolute liability).

\textsuperscript{256} See id. (contending that element of foreseeability must be included in product liability law to avoid turning strict liability into absolute liability).

\textsuperscript{257} See Green, 629 N.W.2d at 745 (contrasting negligence, of which foreseeability is element, and strict product liability, which focuses on defendant's product rather than on defendant's conduct).
social, economic, and political implications, is too harsh. In line with arguments made by S & N in the Wisconsin allergy case, advocates of reasonableness considerations in product liability argue that imposing liability for unknowable risks amounts to absolute liability, making the manufacturer the insurer of his products. In order to prevent strict liability from becoming absolute liability, a minimal element of fault must remain in the interpretation of Section 402A's meaning of "defective condition." Proponents of strict liability argue that strict liability is not absolute liability. Plaintiffs still have to prove the basic elements of a product liability case — causation, defect and injury. Courts that have allowed state-of-the-art evidence find such evidence relevant to the issue of design defective.

The rationale behind imposing no-fault strict liability has been challenged as well. Opponents of strict liability argue that for unknowable risks, the burden of proof rationale is not as

258. See Spradley, supra note 170, at 420 (noting some courts fear that pure strict liability is too harsh and therefore import a notion of reasonableness into strict liability).

259. See Spradley, supra note 170, at 393 (emphasizing that imposition of liability for unknowable risks amounts to absolute liability, forcing manufacturer to be insurer); Schwartz & Tedesco, supra note 249, at 922 (stating dissent in Green decision recognized that Wisconsin was imposing absolute liability by sticking to consumer expectation test).

260. See Robb, supra note 170, at 20 (noting minimal element of fault must remain within Section 402A in order for strict product liability not to become absolute liability); Peter M. Kinkaid & William J. Stuntz, Enforcing Waivers in Products Liability, 69 VA. L. REV. 1111, 1119 (1983) (stating Section 402A requirement that defect exists is essentially fault standard applied to seller's product and does not require absolute liability); William L. Prosser, Fall of the Citadel (Strict Liability to the Consumer), 50 MINN. L. REV. 791, 812 (1966) (concluding strict liability does not apply when product is reasonable safe except for inherent dangers that are unknowable).

261. See Price, supra note 51, at 1279 (stating strict liability, which she refers to as causative liability, is not synonymous with absolute liability); Wertheimer, supra note 170, at 1189 (pointing out that strict liability was never intended to be absolute liability).

262. See Price, supra note 51, at 1279 (stressing plaintiff still have to prove cause-in-fact and proximate cause); Wertheimer, supra note 170, at 1189 (commenting requirement that plaintiff prove defect is significant barrier between strict liability and absolute liability).

263. See MADDEN & OWEN § 10:5, supra note 222, at 631-32 (discussing use of state-of-the-art evidence to demonstrate technological or scientific feasibility); Vargo, supra note 186 (providing fifty state survey on design defect cases including treatment of state-of-the-art evidence).

264. See Spradley, supra note 170, at 394-98 (challenging policies supporting application of strict liability); Robb, supra note 170, at 30-33 (arguing that strict product liability has become absolute liability).
persuasive since manufacturers do not have control over product risks. Similarly, the loss-spreading rationale does not seem to apply to unknowable risks, which are speculative at best. Manufacturers cannot estimate the amount of loss or how often it may occur in order to spread the cost. Specifically, innovators would have a hard time finding adequate insurance coverage at reasonable costs since insurers of manufacturers are forced to charge high premiums in order to preserve a comfortable safety margin to cover unknown risks. In terms of accident minimization, commentators have argued that imposition of liability for unknown risks will not deter, since it is not possible to design around unknown risks. Furthermore, even large manufacturers have limited resources. It is therefore unrealistic to expect manufacturers to concentrate on one or even a few problems, especially when such a manufacturer is likely to expect hundreds of lawsuits every year based on any design theory it may mar-


266. See Spradley, supra note 170, at 394 (commenting on speculative nature of unknowable risks); Schwartz & Tedesco, supra note 249, at 933 (noting that manufacturers' attempt at safety improvement would be guess-work if they are attempting to avoid unknowable risks since manufacturers do not know what they are trying to avoid); RESTATEMENT (THIRD) § 2, cmt. a (1998) (asserting imposition of liability for unforeseeable risks might provide incentive for manufacturer to invest in safety, but such investment would be based on guesswork).

267. See Spradley, supra note 170, at 394 (noting manufacturers cannot estimate amount or frequency of loss and therefore cannot spread loss from unknown risk); Victor E. Schwartz, The Death of "Super Strict Liability" Common Sense Returns to Tort Law, 27 Gonz. L. Rev. 179, 188 (1991) (noting California Supreme Court's concern that imposition of liability for unknowable risks creates problems with insurability).

268. See Ann, supra note 265, at 182 (remarking on inability of innovators to find reasonably priced insurance coverage because of high premiums charged by insurers to shield itself form incalculable risks); Schwartz, supra note 267, at 188 (describing California Supreme Court's argument that imposing liability for unknowable risks would create insurability problems for manufacturers).

269. See Spradley, supra note 170, at 409 (declaring technologically impossible design changes cannot be made); Schwartz, supra note 267, at 183 (arguing that demanding manufactures to make products safer than scientifically or technically possible is unsound public policy).

270. See Spradley, supra note 170, at 410 (noting limited resources of manufacturers); Edward T. O'Donnell, Design Litigation and the State of the Art: Terminology, Practice and Reform, 11 Akron L. Rev. 627, 645-46 (1978) (remarking on difficulty of manufacturer to focus resources on one problem).
In fact, such liability will discourage manufacturers from marketing new products with unknown risks thereby reducing consumer choice by making lower priced product unavailable.\footnote{271}

2. Direction of the Restatement (Third)

In March 1992, the American Law Institute announced its intentions to revise Section 402A.\footnote{272} Of particular interest was the future development of strict product liability in design defect cases.\footnote{273} More than five years later, on May 20, 1997, the final draft of the Restatement (Third) was adopted.\footnote{274} Significantly, the Restatement (Third) adopted the risk-utility analysis for design defectiveness\footnote{275} and relegated the consumer expectation test to \textit{res ipsa}-type defect cases.\footnote{276} Section 2(b) of Restatement (Third) defines design defectiveness in terms of the foreseeable risks of harm and a reasonable alternative design,\footnote{277} essentially adopting

\begin{quote}
\footnote{271. See Spradley, supra note 170, at 410 (stating even large manufacturers cannot focus its resources on one or, on few problems, since they are likely to expect hundreds of lawsuits each year); O'Donnell, supra note 270, at 645-46 (noting large manufacturers expect dozens or hundreds of lawsuit each year based on variety of theories, making it difficult to concentrate resources on any single problem, or even few).}

\footnote{272. See Spradley, supra note 170, at 396 (arguing that liability for unknown risks discourage marketing of new products); Robb supra note 170, at 32 (noting manufacturers are less likely to market products that are not as safe but are less expensive).}

\footnote{273. See Vargo, supra note 186, at 514 (explaining ALI announced plans to revise Section 402A); Aaron Twerski, From a Reporter's Perspective: A Proposed Agenda, 10 TOURO L. REV. 5, 5 n.2 (1993) (stating ALI announced plans to revise Section 402A on March 18, 1992).}


\footnote{275. See Lavelle, supra note 196, at 1059 (providing date Restatement (Third) was adopted); Kysar, supra note 189, at 1702 (reporting date Restatement (Third) was adopted).}

\footnote{276. See Henderson & Twerski, supra note 274, at 672-74 (stating that after review of case law and commentary, majority approach and only sensible method for determining design defective is risk-utility approach). See also Owen, supra note 189, at 758 (noting that risk-utility balancing test is adopted).}

\footnote{277. See Henderson & Twerski, supra note 274, at 678 (asserting consumer expectation test is recognized for \textit{res-ipsa} type cases only). See also James A. Henderson, Jr. & Aaron D. Twerski, Intuition and Technology in Product Design Litigation: An Essay on Proximate Causation, 88 GEO. L.J. 659, 671-72 (2000) (describing \textit{res ipsa} products cases where consumer expectations may still be used).}

\footnote{278. See RESTATEMENT (THIRD) §2(b) (defining design defectiveness). Section 2(b) states:}

A product is defective in design when the foreseeable risks of harm posed by
a *de facto* state-of-the-art limitation on design obligations.\(^{279}\) The United States' trend towards the *Restatement (Third)*\(^{280}\) has prompted at least one commentator to state that U.S. product liability law has returned to its negligence roots.\(^{281}\)

**C. Interpretation of the Development Risk Defense Causes Unrest in the EC**

Of all the provisions in the Directive, the development risk defense has arguably created the most controversy.\(^{282}\) It is one of two provisions from which Member States may derogate.\(^{283}\) As

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Id. *See also* Owen, *supra* note 189, at 755 (discussing definition provided in Section 2(b)).

\(^{279}\) *See* Madden & Owen, *supra* note 222, at § 10:8, 669 (stating *Restatement (Third)* incorporates concept of state-of-the-art as part of its precept of reasonableness); Vandall, *supra* note 178, at 1203 (commenting *Restatement (Third)* will expand use of state-of-the-art defense); Owen, *supra* note 189, at 783 (noting *Restatement (Third)* takes position that state-of-the-art is consistent with developing law).

\(^{280}\) *See* Henderson & Twerski, *supra* note 277, at 672-74 (asserting examination of case law and academic literature demonstrated strong majority of jurisdictions use risk-utility standard for determining design defectiveness). The *Restatement (Third)* reporters state that the overwhelming majority of jurisdictions have adopted the risk-utility test and that the *Restatement (Third)* merely represents the majority rule. Id. However, others have criticized the reporters for drafting the new restatement according to their own views. *See* Lavelle, *supra* note 196, at 1101 (criticizing Reporters of *Restatement (Third)* for making *Restatement (Third)* brief in support of their personal views); Vargo, *supra* note 186, at 558 (commenting on fallacies of method by which Reporters determined that majority of states have gone to risk-utility test).

\(^{281}\) *See* Awad, *supra* note 156, at 276 (observing retreat of U.S. product liability law back to negligence); Owen, *supra* note 186, at 723 (praising return of fault to its natural position at heart of tort law).

\(^{282}\) *See* Howells, *supra* note 17, at 39-40 (remarking that inclusion of development risk defense has caused most controversy); Hodges, *Unanswered Questions, supra* note 49, at 560 (pointing out development risks defense has aroused most interest); Linger, *supra* note 14, at 490 (noting controversial nature of development risk defense).

\(^{283}\) *See* Linger, *supra* note 14, at 485 (noting three optional provisions set forth by Directive); Hans Claudius Taschner, *A Different Path: Consumer Expectation Applied in the European Community Compared with the ALI Restatement Of Third, Torts: Products Liability*, 221, 222-23 (ALI-ABA Course of Study, July 22, 1999) (noting Article 15 of Directive grants three options for derogation). Originally, there were three provisions that were optional: the development risks defense, the setting of financial limits, and the coverage of primary agricultural product. *Id.* The Council Directive 1999/34 of 10 May 1999 eliminated coverage of primary agricultural product as an option. *See* Stapleton, *Bugs in Products Liability, supra* note 34, at 1237 (observing removal of possibility that Member State could bar claims concerning unprocessed primary products); *Directive on Liability*
mentioned previously, UK implementation of the development risk defense became the focus of debate for commentators. The recent study performed by Lovell suggests that producers of innovative products are starting to push for the U.S. approach for development risks reflected in the Restatement (Third) — a negligence based standard. Given its narrow interpretation in national courts however, many practitioners and academics to view the development risk defense as having little practical value to producers.

1. Can Development Risk Really Exist in a Strict Product Liability Regime?

Professors Henderson and Twerski argue that the development risk defense cannot exist within a strict liability system. They particularly criticized Europe for following outdated 402A. While the EC crafted its Directive in a manner reflecting lessons learned from three decades of product liability law in the United States, it followed outdated 1960s U.S. rhetoric of strict liability. As an example of the backwardness of the EC Directive, Professors Henderson & Twerski cite the language of

for Defective Products, supra note 34 (stating that Directive 1999/34/EC eliminated possibility of derogation for primary agricultural products in aftermath of mad cow crisis).

284. See also, Hodges, Unanswered Questions, supra note 49, at 563-69 (analyzing Commission v. United Kingdom); Howells & Mildred, supra note 39, at 1000-10 (detailing Commission v. United Kingdom); Stapleton, Myths of Reform, supra note 13, at 58-60 (commenting on Commission v. United Kingdom).

285. See Lovell’s Study, supra note 66, at 52 (noting arguments by producers that strict liability standard is inappropriate for design defects); European Product Liability Review, Lovell’s Newsletter, Sept. 2003, at 8, available at http://www.lovels.com/control/PublicationControl/pulbd/412/pubType/Newsletter (summarizing concerns of commentators that U.S. and European product liability law is drifting apart).

286. See Lovell’s Study, supra note 66, at 50 (observing that many lawyers and academics view development risk defense as having little practical value to producers because of its narrow reading); Meltzer, supra note 66, at 48 (reporting that narrow reading of development risk defense has caused many lawyers and academics to view development risk defense as having little practical value).

287. See Henderson & Twerski, supra note 17, at 13-14 (criticizing development risk defense as following outdated Restatement (Second)).

288. See id. at 12-13 (predicting Europe will run into many of same conceptual problems that had plagued U.S. product liability law from 1965 into 1990).

289. See id. at 13 (asserting that definition of “producer,” admissibility of post-sale modifications, and liability of manufacturers of component part reflect developments in U.S. law).

290. See id. (noting Europe is moving to strict liability, following “1960s American rhetoric” while the United States is moving in the opposite direction).
the development risk defense, which they argue is focused on manufacturing defects. They assert that although risks may be discovered, design defects require a value judgment, a risk-utility judgment. Thus, the reference to "discovering the defect" in the development risk defense suggests focus on Section 402A rather than the U.S. efforts to correct 402A's deficiencies in dealing with design defects.

2. Return to Negligence or Adherence to Strict Liability?

The United Kingdom's implementation of the development risk defense in Section 4(1)(e) of the Consumer Protection Act of 1987 opened a debate on the development risk defense. As mentioned above, although the United Kingdom implemented the Directive through the Act, its wording deviated from the original text of the Directive. Christopher Newdick considered that the United Kingdom government was correct in advocating a reasonableness standard for the discovery of product defects with regards to development risks, instead of limiting the defense to producers who show that the defect was previously identified.

Advocating a broader interpretation of the development

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291. See id. (stating "[c]learly, the drafters of the [Article 7(e)] language focused on manufacturing defects, whose existence can be discovered empirically in the same manner that one can discover that a cup of tea is near boiling temperature").

292. See Henderson & Twerski, supra note 17, at 13 (arguing that defects are not "discovered," rather designs are evaluated to determine whether they are defective).

293. See Directive, supra note 11, art. 7(e) (setting out development risk defense). Article 7(e) reads "that the state of scientific and technical knowledge at the time when he put the product into circulation was not such as to enable the existence of the defect to be discovered." Id. (emphasis added).

294. See Henderson & Twerski, supra note 17, at 13-14 (chastising Europe for sticking with 402A rather than following U.S. trend toward risk-utility analysis).


296. See Stapleton, Myths of Reform, supra note 18, at 57 (noting deviation in wording of Section 4(1)(e) of Consumer Protection Act from Article 7(e) of Directive). See also Pearl, supra note 38, at 19 (comparing development risk defense as it is set out by Consumer Protection Act with Article 7(e) of Directive).

297. See Consumer Protection Act, supra note 53, § 4(1)(e). Section 4(1)(e) states:

[1]t shall be a defence for him to show that the state of scientific and technical knowledge at the relevant time was not such that a producer of products of the
risk defense, Newdick reasoned that it would be impossible for a defendant to prove "conclusively and absolutely" that there was no knowledge of the defect worldwide. Newdick argued that a narrow interpretation of the defense, allowing such evidence, would impose liability on defendants in an arbitrary manner because liability would be based on the plaintiff’s luck in turning up such information. Newdick goes on to define the scope of the development risk defense by outlining the boundaries of scientific and technical knowledge. He first differentiated between the lack of

same description as the product in question might be expected to have discovered the defect if it had existed in his products while they were under his control. According to Newdick, the UK government asserted that the phrase "a producer of products of the same description as the product in question might be expected to have discovered" in Section 4(1)(e) limits the defense to what the producers could have reasonably discovered. See Newdick, supra note 295, at 459 (discussing UK government’s interpretation of development risk defense); Implementation of E.C. Directive on Product Liability — An Explanatory and Consultative Document 5 (Department of Trade and Industry) (1985) (suggesting reasonableness standard).

298. See id. (asserting impossibility of proving conclusively and absolutely that there is worldwide absence of knowledge of defect); Howells & Mildred, supra note 39, at 1011 (noting Newdick suggests impracticality of proving worldwide absence of knowledge of defect).

299. See Newdick, supra note 295, at 460 (stating reliance on experts would in essence create a strong presumption in favor of defense); Howells & Mildred, supra note 39, at 1011 (noting reliance on expert reliance according to Newdick).

300. See Newdick, supra note 295, at 460 (putting forth hypothetical situation where knowledge of defect of certain material exists in unrelated industry); Howells & Mildred, supra note 39, at 1011 (characterizing Newdick’s example of unpublished evidence of existence of defect as combination of events requiring leap of imagination).

301. See Newdick, supra note 295, at 460 (emphasizing knowledge evidence of defect was found in unrelated industry); Howells & Mildred, supra note 39, at 1011 (noting unrelated industry had knowledge of defect).

302. See Newdick, supra note 295, at 460 (considering unfairness in allowing "unrelated" knowledge to deny development risk defense); Howells & Mildred, supra note 39, at 1011 (outlining Newdick’s argument that allowing in evidence from unrelated industry would be unfair to reasonable producer).

303. See Newdick, supra note 295, at 461-67 (discussing scope of scientific and technical knowledge); Howells & Mildred, supra note 39, at 1012 (critiquing Newdick’s proposed scope of scientific and technical knowledge).
"general" knowledge of unforeseen dangers, which he advanced should not be excused as development risk, and a genuine lack of scientific and technical knowledge. Newdick used refrigerator design as an example of general knowledge. Assuming that it was unforeseeable that children playing inside the refrigerator would die from being locked inside, Newdick argued that the development risk defense would not be applicable to avoid liability for failing to install refrigerator door locks with magnetic catches. He then stated that for scientific and technical knowledge, both (1) the quality and reliability of the information available and (2) the gravity of the danger anticipated from the defect if it were to materialize must be considered in defining the earliest possible point at which knowledge may be imputed to a producer. Thus, knowledge is defined by "the reliable advice of experts," and speculation about a product defect should not trigger producer liability, but something less than scientific certainty should be acceptable. The second consideration took into account the limited resources of the producer and weighed the risk and gravity of injury in determining the obligations of the producer. The two considerations together suggest that knowledge arises when it becomes reasonable for the producer, from the information accumulated, to take action to protect the consumer.

304. See Newdick, supra note 295, at 462 (differentiating between general knowledge and scientific and technical knowledge); A. DIAMOND, COMPARATIVE PRODUCT LIABILITY 42 (C. J. Miller ed., 1986) (discussing example of refrigerators).

305. See Newdick, supra note 295, at 462 (explaining difference between general knowledge and scientific knowledge using refrigerator example).

306. See id. (arguing that development risk defense would not be applicable to liability arising from lack of general knowledge).

307. See id. at 465 (discussing earliest possible moment knowledge may be imputed to producer); Howells & Mildred, supra note 39, at 1012 (describing Newdick's consideration of piecemeal evolution of scientific or technical knowledge).

308. See Newdick, supra note 295, at 455 (explaining quality and reliability of information); Howells & Mildred, supra note 39, at 1012 (considering Newdick's first consideration of quality and reliability of information).

309. See Newdick, supra note 295, at 466 (discussing gravity of danger anticipated from defect if it were to materialize); Howells & Mildred, supra note 39, at 1012 (addressing Newdick's second consideration of gravity of danger).

310. See Newdick, supra note 295, at 466 (remarking on moment producer is deemed to have knowledge); Howells & Mildred, supra note 39, at 1012 (explaining earliest possible moment knowledge may be imputed to producer according to Newdick).
3. Action against the United Kingdom for Failure to Implement the Directive Properly

Almost a decade after Newdick’s article, the European Commission brought action against the United Kingdom for failure to implement the Directive. The European Commission had corresponded with the United Kingdom for six years to no avail and finally brought action for infringements under Article 169 of the EC Treaty. Under Article 169, the European Commission had the burden of proving infringement.

The European Commission submitted that the development risk defense provided for in Section 4(1)(e) of the Act imposed a lighter burden of proof than that imposed by the Directive. Specifically, the Directive allowed the defense only if it was impossible to discover the defect given the state of science.


313. See Pearl, supra note 38, at 19 (noting six years of correspondence between European Commission and United Kingdom before proceeding); Howells & Mildred, supra note 39, at 1000 (reporting six years of unproductive negotiation between European Commission and United Kingdom before proceeding).

314. See Pearl, supra note 38, at 19 (noting infringement proceedings are brought under Article 226 (ex-Article 169); Vincenzi & Fairhurst, supra note 10, at 151 (describing types of infringement that may be brought under Article 226 (ex-Article 169)).


316. Opinion of Advocate General Tesauro, United Kingdom, [1997] E.C.R. at ¶ 7, [1997] 3 C.M.L.R. 927, at ¶ 7 (considering European Commission’s argument that CPA imposes burden of proof that is lighter than that imposed by Directive). See also Pearl, supra note 38, at 19-23 (outlining European Commission’s argument that development risk defense under Section 4(1)(e) of Consumer Protection Act was easier to demonstrate than that of Article 7(e) of Directive).
tific and technical knowledge, whereas Section 4(1)(e) of the Act allowed for the defense as long as the producer is able to show that he complied with the standard precautions of the industry and was not negligent. Thus, the European Commission argued that the United Kingdom implemented a subjective test, whereas the Directive required an objective one.

The United Kingdom argued that the European Commission had misinterpreted the relevant portions of the Directive and the Act, and that Section 4(1)(e) is not substantively different from Article 7(e) of the Directive. The United Kingdom asserted that the only way to make the defense applicable was to interpret it as what the producer should have or could have known given scientific and technical knowledge available.

The United Kingdom argued that such an interpretation is supported by the seventh recital in the preamble to the Directive, which stresses a fair apportionment of risk between the con-

317. See Opinion of Advocate General Tesauro, United Kingdom, [1997] E.C.R. at ¶ 7, [1997] 3 C.M.L.R. 927, at ¶ 7 (comparing language of Consumer Protection Act's Section 4(1)(e) and language of Directive's Article 7(e)). See also Directive, supra note 11, art. 7. Article 7(e) of the Directive states that:

The producer shall not be liable as a result of this Directive if he proves . . . that the state of scientific and technical knowledge at the time when he put the product into circulation was not such as to enable the existence of the defect to be discovered.

Id.; Consumer Protection Act, supra note 53, at § 4(1)(e). Section 4(1)(e) of the Act states:

In any civil proceeding by virtue of this Part against any person ("the person proceeded against") in respect of a defect in a product . . . it shall be a defence for him to show that the state of scientific and technical knowledge at the relevant time was not such that a producer of products of the same description as the product in question might be expected to have discovered the defect if it had existed in his products while they were under his control.

Id.; Pearl, supra note 38, at 19 (comparing Article 7(e) of Directive with Section 4(1)(e) of Consumer Protection Act).

318. See Pearl, supra note 38, at 20 (citing European Commission's submission that Section 4(1)(e) of CPA was more subjective); Hodges, Unanswered Questions, supra note 49, at 564 (noting face of Section (4)(1)(e) wording may seem more subjective).

319. See Opinion of Advocate General Tesauro, United Kingdom, [1997] E.C.R. at ¶ 9, [1997] 3 C.M.L.R. 928, at ¶ 9 (stating argument of UK government that test laid down by Consumer Protection Act is not substantively different from that of Directive); Howells & Mildred, supra note 39, at 1004 (noting United Kingdom replied that tests administered in Consumer Protection Act and Directive were same).

320. See Opinion of Advocate General Tesauro, United Kingdom, [1997] E.C.R. at ¶ 10, [1997] 3 C.M.L.R. 928, at ¶ 10 (advocating that development risks be defined by available scientific and technical knowledge). See also Pearl, supra note 38, at 20-21 (explaining in order for development risk defense to be meaningful, it has to refer to producer's ability to discover defect).
sumer and the producer.  

The Opinion of the AG sought to balance strict liability and the fair apportionment of risk between the injured person and the producer. AG Tesauro recommended that liability should depend on: (1) the state of scientific knowledge; and (2) the accessibility of that knowledge. He concluded that the state of scientific knowledge refers to the most advanced level of research carried out at a given time, including all data available to the scientific community, rather than the views expressed by the majority. The harshness of this definition was tempered by considerations of the accessibility of the information, assessing the opportunity of the information to circulate.

Ultimately, AG Tesauro based his opinion on procedural rather than substantive grounds. Since there was no settled case-law to interpret Section 4(1)(e), the United Kingdom would be seen to infringe upon Article 169 of the EC Treaty only if there is only one possible interpretation of the national provision, and that interpretation conflicts with the Community provi-


322. See Opinion of Advocate General Tesauro, United Kingdom, [1997] E.C.R. at ¶ 10, [1997] 3 C.M.L.R. 928, at ¶¶ 21, 24 (providing for strict liability by defining state of scientific knowledge as most advance level of research and considering apportionment of risk by taking into account accessibility of knowledge).

323. See Howells & Mildred, supra note 39, at 1006-07 (noting AG concluded that test for assigning liability is whether scientific knowledge would permit eradication of defect and actual opportunities for information to circulate); Stapleton, Myths of Reform, supra note 13, at 58 (reporting Court held that two separate aspects of issue had to be considered: state of scientific and technical knowledge and accessibility of that knowledge).

324. See Opinion of Advocate General Tesauro, United Kingdom, [1997] E.C.R. at ¶ 21, [1997] 3 C.M.L.R. 933, at ¶ 21 (holding scientific knowledge refers to most advanced level of research, including all data available to scientific community). See also Howells & Mildred, supra note 39, at 1006-07 (noting AG concluded that state of scientific knowledge refers to most advanced opinion rather than majority view).

325. See Opinion of Advocate General Tesauro, United Kingdom, [1997] E.C.R. at ¶ 24, [1997] 3 C.M.L.R. 933, at ¶ 25 (determining that accessibility of information may be considered when evaluating opportunity for information to circulate). See also Howells & Mildred, supra note 39, at 1007 (noting AG concluded that accessibility of knowledge must be considered as well).

sion. Although Section 4(1)(e) is broader than Article 7(e) of the Directive, there is essentially no clear conflict between the two provisions, especially given Section 1(1) of the Act, which states, "[t]his Part shall have effect for the purpose of making such provision as is necessary to comply with the Product Liability Directive and shall be construed accordingly." On May 29, 1997, the European Court of Justice endorsed the Opinion of AG Tesauro, finding that the European Commission failed to make out its allegation that Section 4(1)(e) of the Act was incompatible with Article 7(e) of the Directive.

4. Academic Debate Regarding Potential Interpretations

The United Kingdom’s implementation of a modified version of the development risk defense sparked a debate among academics regarding the proper interpretation of the defense as it is set out in the Directive. Christopher Hodges and Pro-

327. See Opinion of Advocate General Tesauro, United Kingdom, [1997] E.C.R. at ¶ 14, [1997] 3 C.M.L.R. 933, at ¶ 14 (explaining since there was no case-law interpreting Section 4(1)(e) of Consumer Protection Act, United Kingdom would be held to infringe Article 169 only if there is only one possible interpretation of Section 4(1)(e) which directly conflicts with Article 7(e) of Directive). See also Howells & Mildred, supra note 39, at 1007 (stating there was no irremediable conflict between two provisions).

328. See Opinion of Advocate General Tesauro, United Kingdom, [1997] E.C.R. at ¶¶ 26-28, [1997] 3 C.M.L.R. 933, at ¶¶ 26-28 (noting Section 1 of Consumer Protection Act required national courts to interpret other provisions of the Consumer Protection Act in manner consistent with Directive). See also Howells & Mildred, supra note 39, at 1007 (stating there was no irremediable conflict between two provisions); Pearl, supra note 38, at 21 (noting Section 1(1) of Consumer Protection Act required national court to construe its provisions in manner consistent with Directive).

329. Consumer Protection Act, supra note 53, § 1(1). Hodges, supra note 17, at 648 (interpreting development risk defense in light of Section 1(1) of Consumer Protection Act); Pearl, supra note 38, at 19 (noting interpretation of development risk defense given Section 1(1) of Consumer Protection Act).


331. See Hodges, Unanswered Questions, supra note 49, at 569 (concluding practical interpretation of development risk defense must include concept of reasonableness); Stapleton, Myths of Reform, supra note 13, at 60 (advocating accessibility/reasonableness standard); Howells & Mildred, supra note 39, at 1015 (criticizing AG Tesauro’s introduction of elements of reasonableness and expectation into development risk defense).

Professor Jane Stapleton endorsed broad application of the development risk defense with the purpose of encouraging innovation, while Geraint Howells and Professor Mark Mildred championed strong consumer protection through a narrow interpretation of the defense.333

In a 1998 comment on United Kingdom, Hodges argued that in practice, the development risk defense can only be interpreted by including a concept of reasonableness.334 From a policy perspective, Hodges acknowledged that strict liability was theoretically simpler and cheaper to operate and that insurance may off-set liability.335 Hodges cautioned, however, that the insurance model breaks down when there are unknown risks which cannot be quantified.336 Furthermore, Hodges emphasized the encouragement of innovation as a major aim of the Directive.337 As such, it was not practical to require producers to do repetitive or excessive testing until all possible risks that might occur with the use of a product had been identified.338

the European Commission to study the implementation of the Directive in the EC. See id.

333. See Hodges, Unanswered Questions, supra note 49 (advocating broad application of development risk defense); Stapleton, Myths of Reform, supra note 13 (commenting on necessity of importing reasonableness standard into interpretation of development risk defense); Howells & Mildred, supra note 39 (arguing that development risk defense does not belong in strict liability system). Many scholars, in the United Kingdom and abroad, addressed the issue. However, these four commentator have been especially prolific and have written numerous articles related to the subject. See id.

334. See Hodges, Unanswered Questions, supra note 49, at 569 (concluding practical interpretation of development risk defense must include concept of reasonableness). See also Stapleton, Myths of Reform, supra note 13, at 60 (advocating accessibility/reasonableness standard).

335. See Hodges, Unanswered Questions, supra note 49, at 562 (acknowledging that theoretically, strict liability was simpler and cheaper to operate). See also Explanatory Memorandum, Bulletin European Commission, Supplement II 1976 L. 11 (observing theoretically, strict liability is simpler and cheaper to operate).


337. See Hodges, Unanswered Questions, supra note 49, at 562 (emphasizing major aim of European Union policy is encouragement of innovation). See also Council Decision No. 96/413/EC, O.J. L 167/55 (1996) (stating in Third Recital “Whereas . . . the Council adopted the resolution of 21 November 1994 (4) on the strengthening of the competitiveness of Community industry, which stressed in particular that a competitive innovatory industry in the Community is a prerequisite for lasting economic growth and the creation of new jobs”).

338. See Hodges, Unanswered Questions, supra note 49, at 561 (noting repetitive or
Hodges stated that given practical limitations, it is appropriate for citizens to share some of the development risks involved if they decide to participate in the benefits of the product. The apportionment of risk is thus the policy behind the development risk defense, with the producer bearing the financial risk for compensating injury caused by his defective products, and the consumer bearing the unknown risks of innovation.

Hodges suggested that the standard advocated by the European Commission was so high that it was questionable whether the defense would ever succeed in practice and was therefore contrary to the policy of apportionment of risk. Specifically, Hodges evaluated the European Court of Justice's requirement that the state of scientific and technical knowledge be discoverable with consideration of accessibility of knowledge. Hodges pointed to the Court's importation of the reasonableness test in determining accessibility, then argued that discoverability must also be regulated by the concept of reasonableness, since defects that are discoverable only by extraordinary means are indistinguishable from defects that are absolutely un-

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339. See Hodges, Unanswered Questions, supra note 49, at 562 (stressing appropriateness of consumers sharing development risks since they benefit from product); Stapleton, Myths of Reform, supra note 13, at 60 (noting importance of fair apportionment of risk between injured person and producer as goal set out in Directive).

340. See Hodges, Unanswered Questions, supra note 49, at 563 (pointing out balance of financial risk and development risks between injured person and producer); Stapleton, Myths of Reform, supra note 13, at 60 (emphasizing importance of fair apportionment of risk between injured person and producer as goal set out in Directive).

341. See Hodges, Unanswered Questions, supra note 49, at 565 (stating high standards set by European Commission renders defense useless); Stapleton, Myths of Reform, supra note 13, at 60 (commenting that development risk defense must be interpreted in manner spelt out in CPA or else it would be nugatory defense).

342. See Hodges, Unanswered Questions, supra note 49, at 566 (discussing knowledge on which producer should act); Stapleton, Myths of Reform, supra note 13, at 58-59 (mentioning scope of scientific and technical knowledge).

343. See Hodges, Unanswered Questions, supra note 49, at 565 (describing accessibility of knowledge); Stapleton, Myths of Reform, supra note 13, at 59-60 (commenting on implied requirement of accessibility of knowledge).

344. See Hodges, Unanswered Questions, supra note 49, at 566 (referring to European Court of Justice's holding that accessibility of knowledge requirement is implicit in wording of Article 7(e)); Stapleton, Myths of Reform, supra note 13, at 59-60 (noting importance of accessibility requirement to discoverability of information within state of knowledge).
discoverable.\textsuperscript{345} Professor Stapleton summarized four factors relevant to the scope of scientific and technical knowledge under a "less strained" interpretation of the defense: (1) the relevance of the ideas of those with appropriate scientific and technical facility; (2) the weight to be afforded them; (3) accessibility of knowledge; and (4) the application of known information to a novel context so that knowledge incorporates creative leaps of application and methodology.\textsuperscript{346}

In contrast to Hodges & Professor Stapleton, Geraint Howells & Professor Mark Mildred criticized AG Tesauro as undermining the EC policy of strict product liability.\textsuperscript{347} In a published rebuttal of Hodges arguments for the importation of a reasonableness test in the development risk defense, Howells & Mildred criticized Hodges for putting the interests of innovative producers over those of consumers.\textsuperscript{348} They commented that the issue of insurance is irrelevant to the interpretation of the development risk defense and is a merely part of the cost of business.\textsuperscript{349} Howells & Mildred further argued that the Court's importation of an accessibility requirement is "both gratuitous and illogical."\textsuperscript{350} According to Howells & Mildred, computerized databases allow producers to educate themselves before putting a product in production and circulation.\textsuperscript{351} Thus, if the knowl-

\textsuperscript{345} Hodges, \textit{Unanswered Questions}, supra note 49, at 567 (referring to Jane Stapleton's argument that since virtually everything is discoverable, defense must cover matters discoverable only by extraordinary means in order to achieve fair apportionment of risk). \textit{See also} Howells & Mildred, supra note 39, at 1010 (citing to Jane Stapleton's argument that since virtually everything is discoverable, defense must cover matters discoverable only by extraordinary means).

\textsuperscript{346} \textit{See} Stapleton, \textit{Myths of Reform}, supra note 13, at 59 (stating "[t]hese four factors should, in my view, be sensibly regarded as relevant to whether knowledge has entered the 'state of scientific and technical knowledge').

\textsuperscript{347} \textit{See} Howells & Mildred, supra note 39, at 1015 (lamenting introduction of elements of reasonableness and expectation by AG Tesauro).

\textsuperscript{348} \textit{See} Mildred & Howells, supra note 171, at 570 (asserting Hodges' attempt to prioritize interests of innovative producers moves away from concerns underlying Directive). \textit{See also} Directive, supra note 11, at 29 (referring to Recitals of Directive which list protection of consumers and the fair apportionment of risk \textit{by imposition of liability without fault} as goals).

\textsuperscript{349} \textit{See} Mildred & Howells, supra note 171, at 570 (arguing availability of insurance or lack thereof is no reason to interpret defense one way or other and is merely factor producer considers when deciding to launch product).

\textsuperscript{350} \textit{Id.} at 572 (questioning how knowledge could be discoverable but not available).

\textsuperscript{351} \textit{See id.} (stating "[t]he existence of powerful computerized databases will allow the producer to satisfy itself of the nature of published knowledge in the various fields
edge exists, it is discoverable.\textsuperscript{352}

In another article published the same year, Howells & Mildred recommended that the development risk defense should be repealed all together because it runs counter to the rationale of strict liability.\textsuperscript{353} They criticized Newdick as confusing negligence and strict liability as found in the Directive.\textsuperscript{354} Citing data provided by the First Report of the European Commission on the Directive, Howells & Mildred argued that the fear that insurance would become unavailable or prohibitively expensive under a strict liability regime is unlikely to occur in the Member States.\textsuperscript{355} They reasoned that the modest levels of damages in the Member States, specifically the unavailability of punitive damages in tort claims;\textsuperscript{356} the absence of juries in civil trials;\textsuperscript{357} and the unlawfulness of contingency fees limiting access to legal aid,\textsuperscript{358} all serve to curb the amount of litigation likely to occur in contrast to the situation in the United States.\textsuperscript{359}

\begin{itemize}
  \item[352.] See Mildred & Howells, \textit{supra} note 171, at 572 (asserting that given computerized databases, producers have access to published knowledge before putting a product into circulation).
  \item[353.] See Howells & Mildred, \textit{supra} note 39, at 987 (arguing that defense runs counter to rationale of strict liability).
  \item[354.] See id. at 1011 (stating Newdick’s arguments indicate confusion between negligence and strict liability regimes).
  \item[355.] See id. at 1013 (noting no perceptible increase in insurance premiums of decrease in availability of coverage since Directive came into effect). \textit{See also} First Report, \textit{supra} note 52, at 2 (noting no apparent increase in level of insurance premiums); Report, \textit{supra} note 62, at 11-12 (noting no research had been undertaken to determine impact of Directive on activity of pharmaceutical companies and generally, with exception of Austria, number of demands for policies had not increased considerably).
  \item[356.] See Howells & Mildred, \textit{supra} note 39, at 1013 (commenting on lack of punitive damages in tort cases); Christopher Hodges, Panel discussion at the Washington D.C. Conference (Dec. 1, 2000), \textit{in GREEN PAPER AND THE FUTURE OF PRODUCT LIABILITY LITIGATION IN EUROPE}, Sept. 2001, at 7 [hereinafter Hodges, Panel discussion] (remarking that no European country has punitive damages for product liability claims).
  \item[357.] See Howells & Mildred, \textit{supra} note 39, at 1013 (reporting absence of jury trials in Member States); Hodges, Panel discussion, \textit{supra} note 356, at 7 (remarking that in Europe, juries do not decide questions of liability).
  \item[358.] See Howells & Mildred, \textit{supra} note 39, at 1013 (mentioning unlawfulness of contingency fees in Member States); Hodges, Panel discussion, \textit{supra} note 356, at 7 (noting absence of contingency fees in Member States).
  \item[359.] See Howells & Mildred, \textit{supra} note 39, at 1013-14 (explaining structural difference between European and U.S. litigation systems); Hodges, Panel discussion, \textit{supra} note 356, at 6-7 (reporting differences in legal culture between Europe and United States).
\end{itemize}
5. National Interpretation of Development Risk

To date, only a handful of cases have considered the development risk defense. In a German Supreme Court case, a nine-year old girl was seriously injured when one of the two bottles of mineral water she picked up from her parents’ cellar exploded, causing the glass to shatter. The German Supreme Court rejected the development risk defense holding that the Article 7(e) defense was not available for manufacturing defects. In another German case, several customers were infected with hepatitis A from ingesting a contaminated blackberry cake. The owner of the restaurant asserted that the defect in the cake was undiscoverable. Similar to the German Supreme Court, the appellate court in Germany found the defendant’s argument unconvincing, holding that (1) the defect in the cake was a manufacturing defect and therefore the development risk defense could not be used; and (2) even if the development risk defense existed for the defect, there were scientific tests available that could have detected the virus.

360. See Hodges, Politics, Reform and Reality, supra, note 23, at 123-24 (summarizing decisions in EC on development risk defense); Pearl, supra note 38, at 37-39 (discussing cases considering development risk defense). Hodges states that as of 2000, a total of about thirty cases have been decided in national courts under the Directive, with two in the United Kingdom, one in Ireland and a handful in Austria, Germany, and Spain. Id.


362. See German Law of Torts, supra note 361, at 586 (holding development risk defense applies only to design defects and not manufacturing defects). See also Hodges, Politics, Reform and Reality, supra note 23, at 124 (stating German Supreme Court ruled that development risk defense does not apply to manufacturing defects); Stapleton, International Torts, supra note 230, at 383 (noting Court’s assertion that development risk defense did not apply to manufacturing defects). Manufacturing defects are still under a strict liability system even under the Restatement (Third). Section 2(a) of the Restatement (Third) covering manufacturing defects states that a product is defective if it departs from its intended design, even if all possible care in the preparation and marketing of the product was exercised. See Restatement (Third) §2(a).

363. See Pearl, supra note 38, at 39 (discussing German Blackberry Cake case).

364. See id. (reporting that defect in cake could not be discovered).

365. See id. (holding contaminated cake was manufacturing defect and not eligible for development risk defense, and that even if the defense were available, contaminated cake would not qualify because virus detection tests were available).
In what was the only victory for the development risk defense, a court in the Netherlands found the defendant nonliable for HIV contaminated blood because they had acted in accordance with the scientific and technical knowledge at the time of product circulation. In that case, the plaintiff contracted HIV when he received blood for cardiac surgery. Given the undisputed fact that HIV-1 RNA tests were "elaborate, experimental, and not approved nor validated as a screening test," the court found that the defendant had satisfied his burden of proving the impossibility of discovering that the blood was contaminated.

The courts in the United Kingdom have had several opportunities to consider the development risk defense since the European Court of Justice's decision in United Kingdom. In Abouzaid v. Mothercare (UK) Ltd., Mothercare sold a sleeping bag that was designed to be attached to a child's pushchair with

366. See Lovell's Study, supra note 66, at 50 (reporting only one reported example where development risk defense has been successful); Meltzer, supra note 66, at 48 (pointing out that development risk defense has been successful in only one reported case).


368. See Hodges, Politics, Reform and Reality, supra note 23, at 124 (discussing facts of case).

369. See Hodges, Politics, Reform and Reality, supra note 23, at 125 (discussing holding that development risk applied because defendant proved impossibility of discovering that blood was contaminated). See also A & Others, [2001] 3 All E.R. 289, ¶ 53(iv) (reviewing holding of County Court of Amsterdam, which decided it was not practical at time of blood transfusion to use PCR test as screening test to detect HIV contamination in blood products); Goldberg, supra note 367, 198-99 (commenting on success of development risk defense because it was not possible to detect HIV contamination using HIV-1 RNA test at time of blood donation).


elasticated straps.\textsuperscript{372} In helping his mother attach the sleeping bag to his brother's pushchair, the buckle on an elasticated fastening sprung back hitting the twelve-year-old child in the eye and severely damaging his eyesight.\textsuperscript{373} Mothercare invoked the development risk defense, arguing that there were no records of similar incidents in the Department of Trade and Industry accident database, and that they were unaware of the potential problems with buckle fastening.\textsuperscript{374} Lord Justice Pill of the Supreme Court of Judicature in the Court of Appeals found that knowledge of previous accidents unnecessary to finding an actionable defect.\textsuperscript{375} With regards to the development risk defense, Lord Justice Pill remarked that it is not the Court's role to determine what should have been done.\textsuperscript{376} The important thing was that the public was entitled to expect more from the producer.\textsuperscript{377} In agreement with Lord Justice Pill that the development risk does not apply, Lord Justice Chadwick commented that a simple test would have revealed the defect.\textsuperscript{378} Not having thought of that simple test was not excusable.\textsuperscript{379}
A year later, Mrs. Richardson sued LRC Products when the condom her husband was using failed, causing her to become pregnant. Although the case was dismissed on other grounds, the Queen's Bench Division stated that development risk defense would not have been applicable for known defects, even if the defect could not be determined for every individual product.

Finally, in a case that has caused some debate over the development risk defense, Justice Burton held in A & Others v. National Blood Authority that unknown risks do qualify for the Article 7(e) defense, but unavoidable risks, which are known but unavoidable, do not qualify for the defense. A & Others is a class action suit brought by over a hundred claimants who had been infected with Hepatitis C through blood transfusions. The state of scientific and technical knowledge at the time of infection did not allow the virus to be detected although medical professionals knew of the risk of infection. In a judgment that was not carried out because producer had not thought of it. See also Paula Giliker, Strict Liability for Defective Products: The Ongoing Debate, 24(4) Bus. L.R. 87, 89 (2000) (noting that in Abouzaid case, "discovery" required but a simple, practical test and that "[i]t was no excuse that no-one had thought at the time to undertake this test").

380. See Richardson v. LRC Products Ltd., 2000 Lloyd's Rep. (Med.) 280 (Q.B. Div'l Ct. 2000) (noting Richardson sued manufacturer of condom); Giliker, supra note 379, at 87 (observing case involved failed condom). Mrs. Richardson contends that the fracture of the condom was caused by weakening due to ozone exposure in the factory. See Richardson, 2000 Lloyd's Rep. Med. at 280 (noting Richardson claims condom fracture was due to ozone damaging).

381. See Richardson, 2000 Lloyd's Rep. Med. at 284 (holding evidence did not prove fracture leading to failure of condom was caused by cracks due to ozone exposure). See also Newdick, supra note 295, at 472 (asserting that development risk defense should not be extended to cover problems of quality control).

382. See Richardson, 2000 Lloyd's Rep. Med. at 285 (declaring that development risk defense is not applicable to defects of known character just because there is not test to reveal its existence in every case); A & Others v. The National Blood Authority and Others, 3 All E.R. 289, at ¶ 53(ii) (Q.B. Div'l Ct. 2001) (quoting Richardson as stating that development risk defense does not protect defendant when defect is known).


384. See A & Others, 3 All E.R. 289, at ¶ 78 (stating unknown risks do qualify for development risk defense but known risks, even though unavoidable, do not qualify for defense). See also Consumer Protection Act 1987: Liability for Defective Products, 10(1) Medical L.R. 82, 84 (2002) [hereinafter MLR Summary] (noting that producers are liable for known risk even if risks were unavoidable in particular product).

385. See A & Others, 3 All E.R. 289, at ¶ 1 (noting trial concerns 114 claimants arising who have contracted Hepatitis C infection from blood and blood products). See also Giliker, supra note 379, at 88 (reporting that over 100 claimants brought suit).

386. See MLR Summary, supra note 384, at 82 (noting at time of infection, risk of infection through blood transfusion was impossible to avoid, either because there was
runs over a hundred pages, Justice Burton reviewed the decision of *Commission v. United Kingdom*, went through case law dealing with the development risk defense from other EC countries and considered academic literature on the defense. Burton then concluded that since the risk of infection was known, the producers continued to produce and supply the product at their own risk. Justice Burton went on to construe Article 7(e) as exempting producers from liability when risks are unknown but not when risks are known but unavoidable. Ultimately, Burton held that since the risk of Hepatitis C infection was known, the development risk defense did not apply.

III. THE EC, TAKING THE ROAD LESS TRAVELED BY APPLYING LESSONS FROM THE UNITED STATES

A. The United States Experience

In the United States, product liability law is moving back to a negligence standard for design defect cases. Generally speaking, manufacturers are exempt from liability for design defects that reflect unavoidable risks. Under the *Restatement (Second)*, imposition of liability for unknowable risks depends largely on no way to detect virus in blood or because virus was yet unknown to scientific public). But see Goldberg, supra note 367, at 166-67 (reviewing state of scientific knowledge at time of blood infections).

387. See A & Others, 3 All E.R. 289, at ¶ 53(i) (reviewing European Court of Justice's judgment in *Commission v. United Kingdom*).

388. See id. at ¶ 53(iii) (considering case law from Germany, Netherlands, and Australia).

389. See id. at ¶ 54 (reviewing commentary from academia regarding policy considerations related to development risk defense).

390. See id. at ¶ 74(ii) (stating producers that continue to produce and supply products with known risks do so at their own risk). See also MLR summary, supra note 384, at 88 (noting producers are responsible for known risks).

391. See A & Others, 3 All E.R. 289, at ¶ 78 (explaining unknown risks qualify for development risk defense but known risks do not qualify for defense even if unavoidable). See also MLR Summary, supra note 384, at 84 (remarking that there is liability for known but unavoidable risk).

392. See A & Others, 3 All E.R. 289, at ¶ 84 (concluding that since risk of Hepatitis C infection was known, development risk is not applicable). See also MLR summary, supra note 384, at 88 (noting information about risk of infection of Hepatitis C was available to producers since 1970s).

393. See supra notes 273-81 and accompanying text (observing that *Restatement (Third)* documents U.S. product liability law's shift back to negligence standard).

394. See supra notes 233-35 and accompanying text (noting that *comment k* exempts manufacturers for unavoidably unsafe products).
on whether the consumer expectation standard\textsuperscript{395} or the risk-utility standard is used to access defectiveness.\textsuperscript{396} Jurisdictions applying a pure consumer expectation test tend to staunchly stand by their refusal to consider evidence of the state-of-the-art, which goes to the issue of manufacturer’s conduct rather than the expectation of the consumer.\textsuperscript{397} Risk-utility jurisdictions, on the other hand, find state-of-the-art evidence applicable for the determination of scientific or technological feasibility of a reasonable alternative design.\textsuperscript{398} Since state-of-the-art evidence reflects the limits of scientific or technological knowledge in product development, admissibility of state-of-the-art becomes crucial in predicting liability for defects caused by unknowable risks.\textsuperscript{399} In eliminating the consumer expectation test, the Restatement (Third) has recognized U.S. product liability law’s return to negligence.\textsuperscript{400}

B. The Road Not Taken

Professor Henderson’s dismal prediction that the EC strict product liability experiment will merely repeat the U.S. experience was based on his perception that the EC was taking a road already traveled by the United States.\textsuperscript{401} It is true that consistent with the United States,\textsuperscript{402} the German courts interpreting the Directive have decided that the development risk defense is inapplicable for manufacturing defects.\textsuperscript{403} Furthermore, the ruling

\textsuperscript{395} See supra note 193 and accompanying text (defining consumer expectation test as safety that ordinary consumer expects).

\textsuperscript{396} See supra note 195 and accompanying text (defining risk-utility test as balancing test that considers potential risk of injury and cost to manufacturer of avoiding injuries).

\textsuperscript{397} See supra note 257 and accompanying text (discussing inadmissibility of state-of-the-art evidence under consumer expectation test).

\textsuperscript{398} See supra notes 222-26 and accompanying text (discussing admissibility of state-of-the-art evidence as factor in determining existence of reasonable alternative design).

\textsuperscript{399} See supra notes 251-32 and accompanying text (observing role of state-of-the-art evidence in predicting liability for unknown defects).

\textsuperscript{400} See supra note 281 and accompanying text (reporting how Restatement (Third) reflects U.S. product liability law’s return to negligence).

\textsuperscript{401} See supra notes 288-92 and accompanying text (outlining Henderson’s criticism of EC in basing its Directive on Section 402A of Restatement (Second)).

\textsuperscript{402} See supra note 362 (stating manufacturing defects are still under strict liability system, even under Restatement (Third)).

\textsuperscript{403} See supra notes 361-65 and accompanying text (discussing German cases that do not allow development risk defense for manufacturing defect).
in the Netherlands to allow the defense to insulate suppliers of blood products 404 comports with the U.S. policy of protecting sellers of blood from strict product liability. 405 The similarities end here however.

In Commission v. United Kingdom, the European Court of Justice concluded that liability would depend on the state of scientific knowledge and accessibility to that knowledge. 406 But unlike the state-of-the-art, which at one point varied from being industry custom to the currently accepted definition of scientific and technological feasibility, 407 the European Court of Justice clearly defined the state of scientific knowledge as the most advanced knowledge available in the field. 408

The United Kingdom's ruling in Abouzaid further limits what qualifies as scientific knowledge. 409 The Supreme Court of Judicature in the Court of Appeals imposed liability on the manufacturer despite the fact that no records of similar incidents were found in the Department of Trade and Industry accident database. 410 One interpretation of Abouzaid is that the defectively design elasticated fastening 411 is more like the defectively designed refrigerator in Newdick's article, 412 and would be considered general knowledge rather than scientific and technical knowledge. As proposed by Newdick, the lack of general knowledge should not insulate a manufacturer from liability. 413

404. See supra notes 367-69 and accompanying text (observing Dutch court's decision did not hold blood supplier liable for contaminated blood).
405. See supra note 32 (summarizing U.S. blood shield statutes in insulating sellers of blood from strict product liability).
406. See supra note 323 and accompanying text (reviewing Commission v. United Kingdom where European Court of Justice advanced two-prong test to determine whether liability should be imposed for development risks).
407. See supra notes 201-26 and accompanying text (commenting on various definitions of state-of-the-art).
408. See supra note 324 and accompanying text (defining state of scientific knowledge as most advanced knowledge in field).
409. See supra notes 371-79 and accompanying text (explaining court's decision not to allow development risk defense of defects that may be discovered by simple test).
410. See supra note 374 and accompanying text (reporting lack of records showing accidents involving elasticated fastenings).
411. See supra note 373 and accompanying text (describing case where elasticated fastening sprung back and injured child).
412. See supra notes 305-06 and accompanying text (giving example of what Newdick considers general knowledge).
413. See supra note 304 and accompanying text (remarking on Newdick's proposal that lack of general knowledge does not provide defense for manufacturer, whereas lack scientific/technical knowledge does result in defense).
Additionally, the scope of the development risk defense for design defect cases was outlined by *Richardson v. LRC* and by Justice Burton's ruling in *A & Others*. Read together, the United Kingdom has clearly shown itself willing to impose liability for unavoidable risks, but allows the development risk defense for unknown risks. The United Kingdom's application of the development risk defense contrasts with the U.S. approach of not excusing unknown risks, exemplified by the consumer expectation test, and the forgiveness of *comment k* for unavoidably unsafe products.

The controversies surrounding the development risk defense are unlikely to subside. The differing treatment of contaminated blood in the Netherlands and the United Kingdom portends numerous future debates on the subject. At the present time, analysis of EC trends is limited by the lack of case law in national courts. From what has been decided, it appears that the development risk defense remains applicable for cases where the defect in product design is due to an unknown scientific risk. Those like Professor Henderson may argue that Europe is using the development risk defense as a European *comment k*, in order to carve out a special place for pharmaceutical products. One important difference in the EC interpretation of the development risk defense is that producers

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414. See supra notes 380-82 and accompanying text (deciding case on other grounds but stating that development risk defense was not available for known defects, even if defect could not be determined for every individual product).

415. See supra notes 390-92 and accompanying text (holding development risk defense did not apply because risk of Hepatitis C infection was known).

416. See supra note 391 and accompanying text (construing Article 7(e) as exempting producers from liability for unknown risks but not unavoidable risks).

417. See supra notes 248-57 and accompanying text (exemplifying consumer expectation approach to state-of-the-art evidence).

418. See supra notes 233-36 and accompanying text (discussing *comment k* exemption for unavoidably unsafe products).

419. See supra notes 367-69 and accompanying text (reporting Dutch court's decision not hold blood supplier liability for contaminated blood).

420. See supra notes 383-92 and accompanying text (holding producer liability for contaminated blood because risk of Hepatitis C infection was known).

421. See supra note 360 and accompanying text (noting scarcity of case law interpreting development risk defense).

422. See supra note 391 and accompanying text (observing UK's interpretation of development risk defense exempts producers from liability for unknown risks but not unavoidable risks).

423. See supra notes 233-35 and accompanying text (observing that *comment k* carves out exception for unavoidably safe products).
escape liability for unknown risks, while unavoidable risks are not excused.\textsuperscript{424} Given this compromise, the Directive truly imposes strict, but not absolute liability on producers. Contrary to Professor Henderson's scathing remarks about the backwardness of the EC Directive,\textsuperscript{425} the EC has learned its lesson from the United States and has chosen a deliberate path towards strict liability.

Issues of distinguishing strict liability from negligence aside, the implementation of the development risk defense reflects the priority the EC has given to the strict liability label at the expense of apportionment of risk and encouraging innovation.\textsuperscript{426} The impact on pharmaceutical manufacturers is enormous.\textsuperscript{427} As was feared by Hodges and Professor Stapleton,\textsuperscript{428} the extremely narrow interpretation of the development risk defense has made it essentially worthless to producers.\textsuperscript{429} With pharmaceutical research and development stunted by concerns of liability,\textsuperscript{430} it is arguable that strict liability will ultimately prove to be a win for advocates of consumer protection.

CONCLUSION

What results from national interpretation of the development risk defense is the opportunity for producers to escape liability only when the defect in the product is unknown. The interpretation of the development risk defense by the Member States indicates that unlike the United States, the EC is staying their course on the road to strict liability.

\textsuperscript{424} See \textit{supra} note 391 and accompanying text (reporting that contrary to United States, United Kingdom imposes liability for unavoidable risks but not unknown risks).

\textsuperscript{425} See \textit{supra} notes 288-94 and accompanying text (discussing Henderson's criticism of Directive for following Section 402A of \textit{Restatement (Second)}).

\textsuperscript{426} See \textit{supra} note 340 and accompanying text (arguing that main objective of Directive is apportionment of risk); \textit{supra} note 337 and accompanying text (emphasizing encouragement of innovation as major aim of Directive).

\textsuperscript{427} See \textit{supra} note 13 and accompanying text (noting importance of development risk defense to pharmaceutical sector).

\textsuperscript{428} See \textit{supra} note 341 and accompanying text (arguing narrow interpretation of defense would be make it impracticable).

\textsuperscript{429} See \textit{supra} note 286 and accompanying text (pointing out that many practitioners and academics feel that narrow interpreting of defense has made it defense of little value).

\textsuperscript{430} See \textit{supra} note 8 and accompanying text (stating United States' decision not to impose strict liability was based on concern with deterring effect of strict liability on innovation).