Fordham International Law Journal

Volume 27, *Issue* 6 2003 *Article* 4

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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.[1] Payne was prescribed Prozac to treat the depression that had developed after his retirement.[2] On the eleventh day of his Prozac treatment, Payne suffocated his wife then threw himself off a cliff near their home.[3] 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.[4] Hundreds of similar cases have been brought against

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1. *See Body Found*, SUNDAY TIMES, Mar. 17, 1996, at Home News (reporting finding of Payne's body). *See also* Robert Verkaik, *The Paynes Expected a Peaceful Retirement. It Ended in Violent Death. But Was Prozac to Blame?*, INDEPENDENT (LONDON), Dec. 4, 2000, at 3 (detailing events leading to Reginald Payne's murder of his wife and his subsequent suicide).

2. *See* Verkaik, *supra* note 1, at 3 (explaining Payne had developed depression after retiring from his job as teacher); Angela M. Walker, *R[x]: 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.[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 *comment k*,[6] exempting them from strict product liability.[7] The concern underlying the *comment k* exception is the impact of imposing strict liability on the pharmaceutical sector and the deterring effect on innovation of new drugs.[8] Under *comment k*, manufacturers of drug products are held to a negligence standard rather than to strict liability.[9]

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supra note 2, at 790 (asserting that as of February 14, 2002, Payne's case is first Prozac product liability lawsuit in Great Britain).

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, *Fluoxetine-Induced Suicidal Ideation: An Examination of the Medical Literature, Case Law, and the Legal Liability of Drug Manufacturers*, 57 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 *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).

6. *See* RESTATEMENT (SECOND) OF TORTS [hereinafter 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 *comment k* which imposes negligence standard for unavoidably safe products like Prozac).

7. *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 unsafe products); JAMES A. HENDERSON & AARON D. TWERSKI, PRODUCTS LIABILITY, PROBLEMS AND PROCESS 456 (4th ed. 2000) (1938) (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).

8. *See* RESTATEMENT (SECOND), cmt. k (pointing to pharmaceutical sector as specific example of industry directly impacted by *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).

9. *See* Brown v. Superior Court (Abbott Laboratories), 751 P.2d 470, 475 (Cal. 1988) (asserting *comment k* is based on principles of negligence). *See also* Victor E. Schwartz, *Unavoidably Unsafe Products: Clarifying the Meaning and Policy Behind Comment K*, 42 WASH. & LEE L. REV. 1139, 1141 (1985) (explaining *Restatement (Third) of Torts: Products Liability* ("*Restatement (Third)*") authors believed that negligence law was adequate for design of drugs).

In the European Community ("EC"),[10] product liability law is governed by the Product Liability Directive 85/374 ("Directive"),[11] which imposes strict liability on manufacturers of defective products but allows an exception to liability for development risks.[12] 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.[13] The implementation of the development risk defense in the EC has been quite contentious.[14] The defense has been accused of blurring the line between strict liability and negligence.

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.[15] 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) (1998) (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.

11. Council Directive No. 85/374, O.J. L 210/29 (1985) [hereinafter Directive].

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).

14. *See* HENDERSON & TWERSKI, *supra* note 7, at 707 (declaring implementation of development risk provision to be most controversial issue in EC); Lori M. Linger, *The Products Liability Directive: A Mandatory Development Risks Defense*, 14 FORDHAM INT'L L.J. 478, 490 (1991) (remarking on controversy caused by implementation of development risk defense).

15. *See* James A. Henderson, Jr., *Why Negligence Dominates Tort*, 50 UCLA L. REV.

Restatement (Third): Products Liability ("*Restatement (Third)*") may cause some to wonder if such distinction matters.[16] For product liability in the EC, the distinction between the strict liability and negligence regime is of critical importance.[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.[18] Bernstein asserted that under the Directive, three parallel laboratory experiments will be run giving observers the opportunity to consider: (1) the shift from *de facto* strict liability to *de jure* strict product liability;[19] (2) the move

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377, 380-82 (2002) (outlining negligence-strict liability debate); Richard L. Cupp, Jr. & Danielle Polage, *The Rhetoric of Strict Products Liability Versus Negligence: An Empirical Analysis*, 77 N.Y.U. L. REV. 874 (2002) (remarking on questionable distinction between negligence and strict liability in design defect cases); Anita Bernstein, *Looking at Europe for the Difference Between Strict and Fault-Based Liability*, 14 J. PRODUCTS LIABILITY 207, 207 (1992) (commenting on scholarly discussion of difference between strict product liability and negligence based liability); Gary T. Schwartz, *The Beginning and the Possible End of the Rise of Modern American Tort Law*, 26 GA. L. REV. 601, 654-56 (1992) (describing shift of tort law from negligence to strict liability and outlining gradual rejection of strict product liability, especially in design defect cases); John Montgomery & David G. Owen, *Reflections on the Theory and Administration of Strict Tort Liability for Defect Products*, 27 S.C. L. REV. 803, 810 (1976) (pointing out imposition of seller liability despite exercise of all possible care distinguishes strict liability from traditional negligence law). *See generally* Guido Calabresi & Jon T. Hirschoff, *Toward a Test for Strict Liability in Torts*, 81 YALE L.J. 1055 (1972) (discussing Judge Learned Hand's test for fault and application of strict liability).

16. *See* RESTATEMENT (THIRD): PRODUCTS LIABILITY [hereinafter RESTATMENT (THIRD)]. *See also* Cupp & Polage, *supra* note 15, at 874 (noting *Restatement (Third)* subjects product liability claims to negligence analysis); Henderson, *supra* note 15, at 404-05 (arguing negligence, not strict liability, is only viable concept for product liability and is represented by *Restatement (Third)*).

17. *See* James A. Henderson, Jr. & Aaron D. Twerski, *What Europe, Japan, and Other Countries Can Learn From the New American Restatement of Products Liability*, 34 TEX. INT'L L.J. 1 (1999) (criticizing Europe for sticking to strict liability while United States heads back to negligence); CHRISTOPHER J.S. HODGES, PRODUCT LIABILITY EUROPEAN LAWS AND PRACTICE 6-8 (1993) (discussing European move to strict liability and its benefits); GERAINT HOWELLS, COMPARATIVE PRODUCT LIABILITY 311-22 (1993) (distinguishing between strict product liability and negligence based liability and considerations supporting each). For general information on European product liability, see WILLIAM C. HOFFMAN & SUSANNE HILL-ARNING, GUIDE TO PRODUCT LIABILITY IN EUROPE (1994); PATRICK KELLY & REBECCA ATTREE, EUROPEAN PRODUCT LIABILITY (1992).

18. *See* Bernstein, *supra* note 15, at 213 (asserting EC move to strict liability will provide opportunity to study meaning of strict liability).

19. *See* Bernstein, *supra* note 15, at 212 (noting France and Luxembourg have *de facto* strict liability); Hans C. Taschner, *Product Liability in Europe: Future Prospects, in EEC Strict Liability in 1992*, at 84 (PLI Litig. & Admin. Practice Course Handbook Series No. 371, 1989) (noting France and Luxembourg have *de facto* strict liability).

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

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).

23. *See* Henderson & Twerski, *supra* note 17, at 20 (criticizing Europe for sticking to strict liability while United States heads back to negligence); Christopher J. S. Hodges, *Product Liability in Europe: Politics, Reform and Reality*, 27 WM. MITCHELL L. REV. 121, 123-24 (2000) [hereinafter Hodges, *Politics, Reform and Reality*] (outlining recent case law in Europe).

24. *See* Directive, *supra* note 11 (establishing product liability law for EC).

States.[25] The Directive did not preempt product liability law in the Member States,[26] but instead, sought to supplement existing law to the extent that it was consistent with the Directive.[27] Two basic goals of the Directive are discernable from the Preamble of the Directive:[28] (1) to promote the free movement of goods by

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25. *See* VINCENZI & FAIRHURST, *supra* note 10, at 37 (stating directives leave implementation to Member States); John G. Culhane, *The Limits of Product Liability Reform Within a Consumer Expectation Model: A Comparison of Approaches Taken by the United States and the European Union*, 19 HASTINGS INT'L & COMP. L. REV. 1, 29 (1995) (explaining that directives establish community policy but leave implementation to Member State).

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).

27. *See* Sandra N. Hurd & Frances E. Zollers, *Desperately Seeking Harmony: The European Community's Search for Uniformity in Product Liability Law*, 30 AM. BUS. L.J. 35, 41 (1992) (remarking Directive supplements rather than preempts Member State product liability law to extent that Member State law is consistent with the Directive); Andrew C. Spacone, *Strict Liability in the European Union*, 5 ROGER WILLIAMS U. L. REV. 341, 351 (2000) (stating Directive supplements various Member States' liability schemes but does not replace it).

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;[29] and (2) to protect consumers by establishing a strict product liability system.[30]

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.[31] Article 2 defines *product* as "all movables . . . even though incorporated into another movable or into an immovable."[32] Electricity is specifically included as a "product,"[33] and while the original scope of the Directive did not include primary agricultural products, such items were defined as products after

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bility of the producer for damage caused by the defectiveness of his products is necessary because the existing divergences may distort competition and affect the movement of goods within the common market and entail a differing degree of protection of the consumer against damage caused by a defective product to his health or property.

Whereas liability without fault on the part of the producer is the sole means of adequately solving the problem, peculiar to our age of increasing technicality, of a fair apportionment of the risks inherent in modern technological production.

Id. *See* HOWELLS, *supra* note 17, at 29 (1993) (stating Directive has two discernable goals and citing Preamble of Directive).

29. *See* Warren Freedman, *European Community Law, Strasbourg Convention, EEC Draft Directive, and Harmonization Efforts in Products Liability* 8 (Report published on the occasion of its 12th Biennial Conference on the Law of the World in Berlin, West Germany, The World Peace Through Law Center, July 21-26, 1985) (stating EEC Draft Directive on Product Liability sought to harmonize national laws on product liability and promote free flow of products); Mary J. Davis, *Individual and Institutional Responsibility: A Vision for Comparative Fault in Products Liability*, 39 VILL. L. REV. 281, 332 (1994) (asserting one main focus of Directive was to prevent distorted competition among Member States that had divergent national laws).

30. *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).

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

32. *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* HODGES, *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 statues 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).

33. Directive, *supra* note 11, art. 2.

the "mad cow" crisis.[34] *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.[35] In addition, anyone who imports a product that falls under Article 2 can also be held liable.[36] Persons involved in the production chain, such as suppliers and retailers are not liable as long as they can identify a producer.[37] 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.[38]

This *defect* is tied to consumer expectation[39] and is defined

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34. *See* Jane Stapleton, *Bugs in Anglo-American Products Liability*, 53 S.C. L. REV. 1225, 1234-37 (2002) [hereinafter Stapleton, *Bugs in Products Liability*] (discussing impact of mad cow crisis in England and amendment of Directive in response to poor handling of crisis by Member States). The scope of the Directive was extended by Council Directive No. 1999/34/EC, O.J. L 141/20, at 20-21 (1999). *See Directive on Liability for Defective Products* (Consumer Affairs, European Commission), *available at* http://europa.eu.int/comm/consumers/cons_safe/prod_safe/defect_prod/directive_en.htm (last visited Apr. 12, 2004) (stating that Directive 1999/34/EC eliminated possibility of derogation for primary agricultural products in aftermath of mad cow crisis).

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).

36. *See* Directive, *supra* note 11, art. 3, § 2 (making importers of defective products liable). *See also* Hans Claudius Taschner, *Harmonization of Product Liability Law in European Community*, 34 TEX. INT'L L.J. 21, 30 (1999) (stating Article 3(2) covers anyone importing products into Community, although imports within EC are not covered); Mark Mildred, *Litigation Rules and Culture: The European Perspective*, 23 N.Y.U. REV. L & SOC. CHANGE 433, 436 (1997) (noting importers of defective products are held liable under Article 3(2)).

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).

39. *See* Geraint G. Howells & Mark Mildred, *Is European Products Liability More Protective Than the Restatement (Third) of Torts: Products Liability?*, 65 TENN. L. REV. 985, 994

in Article 6, Section 1 of the Directive.[40] 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.[41] Thus, an objective, rather than a subjective test is used.[42] Article 6(1)(b), however, stipulates that the product must have been used in a reasonable way[43] and (1)(c) includes the age of the product as an additional factor.[44] 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.[45]

2. Defenses to Liability Under the Directive

Article 7 of the Directive sets out six defenses to strict prod-

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(1998) (stating Directive adopts the consumer expectation standard); HODGES, *supra* note 17, at 52 (observing consumer expectation test is adopted).

40. *See* Directive, *supra* note 11, art. 6, § 1 (defining *defect*). Article 6(1) of the Directive provides:

> A product is defective when it does not provide the safety which a person is entitled to expect, taking all circumstances into account, including:
> (a) the presentation of the product;
> (b) the use to which it could reasonably be expected that the product would be put; and
> (c) the time when the product was put into circulation.

Id. The Directive does not seem to differentiate between manufacturing and design defects although the committee drafting the Directive did expressly indicate that Article 6(1)(a) would encompass failure to warn or instruct type defects. *See* Ferdinando Albanese & Louis F. Del Duca, *Developments in European Product Liability*, 5 DICK. J. INT'L L. 193, 209 (1987) (noting committee did not wish to enumerate three types of defects but did expressly indicate that incorrect or incomplete directions or use of warning would be covered by the notion of defect); Taschner, *supra* note 36, at 30 (stating Directive does not distinguish among three categories of defect).

41. *See* HODGES, *supra* note 17, at 52 (pointing out wording of Article 6 does not distinguish between producer and consumer); Taschner, *supra* note 36, at 30 (remarking expectation is that of consumer).

42. *See* HODGES, *supra* note 17, at 52 (noting objective test on defectiveness is adopted); Taschner, *supra* note 36, at 30 (stating concept of defect is objective one).

43. *See* Directive, *supra* note 11, art. 6, § 1(b) (stipulating that reasonable expected use must be considered). *See also* HODGES, *supra* note 17, at 54 (listing reasonably expected use as factor that must be considered); HOWELLS, *supra* note 17, at 38 (explaining Directive covers reasonably expected use and foreseeable misuse).

44. *See* Directive, *supra* note 11, art. 6, § 1(c) (providing that time product was put into circulation must be considered). *See also* HODGES, *supra* note 17, at 54 (reporting products that become dangerous after extensive use or after reasonable or state life would not be found defective); Mildred, *supra* note 36, 436 (noting age of product is one relevant factor in determining defectiveness).

45. *See* Directive, *supra* note 11, art. 6, § 2 (stating subsequent circulation of better product does not mean that product in question is defective).

uct liability.[46] 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.[47] Section (d) accepts compliance with mandatory regulations issued by public authorities as a complete defense to strict liability.[48]

The development risk defense, set out in (e), is the most controversial.[49] 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.[50]

The development risk defense was inserted as an optional provision which may be derogated by Member States.[51]

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

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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.[52] Austria, Belgium, Denmark, Germany, Greece, Ireland, Italy, Netherlands, Portugal, Sweden and the United Kingdom included the development risk defense;[53] Spain included the defense though excluded medicines, food or food products intended for human consumption from its ambit;[54] and Finland and Luxembourg ex-

52. *See* On the Application of Council Directive on the Approximation of Laws, Regulations and Administrative Provisions of the Member States Concerning Liability for Defective Products: First Report from the Commission of the European Communities, COM (95)617 final [hereinafter First Report] (commenting that all Member States had taken measure to implement Directive with exception of France); *Product Liability: Commission Adopts Report on Defective Products*, EUR. ENV'T, Jan. 8, 1996, at 468 (stating France had not taken measure to incorporate Directive into national law).

53. *See* Austria: 99th Bundesgesetz vom 21. Jänner 1988 über die Haftung für ein fehlerhaftes Produkt [99th Federal Act of 21 January 1988 on the Liability for a Defective Product], § 8(2) (detailing exclusion of liability for development risks); Belgium: Loi relative à la responsabilité du fait des produits défectueux du 25 février 1991 [Law on the Civil Liability for Defective Products of 25 February 1992], art. 8(e) (providing for development risk defense); Denmark: Lov nr. 371 af 7 juni 1989 om produktansvar [Law Concerning Products Liability of 7 June 1989], ch. 3, § 7(4) (outlining exemption from liability due to development risks); Germany: Gesetz über die Haftung für fehlerhafte Produkte vom 15. Dezember 1989 [Law Concerning Liability for Defective Products of 15 December 1989], § 1(2)(5) (carving out exception to liability for development risks) [hereinafter Germany's Product Liability Act]; Greece: Act no. 1961 of 3 September 1991 on Consumer Protection and Other Provisions, *amended by* Act No. 2000 of 24 December 1991, Government Gazette A 132, ch. 3, art. 10(e) (exonerating producers of liability due to development risks); Ireland: An Bille um Dhliteanas I Leith Táirgí Fabhtacha, 1991, Liability for Defective Products Bill, 1991, § 6(e) (exempting producers from liability for development risks); Italy: Decreto del Presidente della Repubblica 24º maggio 1988 n. 224 [Presidential Decree of 24 May 1988], art. 6, § 1(e) (excluding liability for development risks); Netherlands: Produktenaansprakelijkheid [Product Liability Act], bk. 6, tit. 3, ch. 3, art. 185, § 1(e) (outlining development risk defense); Portugal: Decreto-lei n.º 383/89 de 6 de Novembro, [Decree — Law no. 383.89 of 6 November 1989], art. 5(e) (providing development risk provision); Sweden: Produktansvarslag SFS 1992:18, SFS 1992:1137 [Product Liability Act 1992:18] as *amended by* 1992:1137, § 8(4) (allowing exception to liability for development risks); United Kingdom: Consumer Protect Act 1987 [hereinafter Consumer Protection Act], ch. 43, pt. 1, § 4(1)(e) (absolving producers of liability due to development risks). For general information on Acts implementing the Directive, see HODGES, *supra* note 17 (translating and discussing acts of Member States implementing Directive); HOFFMAN & HILL-ARNING, *supra* note 17 (outlining Member State implementation of Directive and providing translated copies of national acts).

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).

cluded the defense altogether.[55]

3. The Green Paper on Liability for Defective Products

In 1999, the European Commission adopted the Green Paper on Liability for Defective Products.[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.[57] Among the issues considered were implementation of the development risks defense and consideration of its abolition.[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.[59] The Green Paper also asserted that whether or not to include the development risk defense delayed the adoption of the Directive by France.[60] France ultimately joined the majority of Member States in allowing a development risk defense apart

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).

56. Liability for Defective Products: Green Paper from the Commission of the European Communities, COM (1999) 396 final [hereinafter Green Paper].

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).

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

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).

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.[61]

The European Commission's Report in 2000 considered reactions to the Green Paper.[62] Specifically, the Report considered data from the five Member States that allowed partial or total liability for development risks.[63] As of 2000, very little data was available to determine the practical impact of imposing liability for development risks.[64] An updated report is expected in 2005.[65]

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.[66] Twelve conclusions were made based on the Study.[67] Lovell's determined that the number of product liability claims in the EC had increased noticeably in the last ten years.[68] The increase in claims was mainly attributed to

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61. *See* Loi nº 98-389 du 19 mai 1998 relatives à la responsabilité du fait des produits défectueux, art. 12 [Law No. 98-389 of May 19, 1998 on the Civil Liability for Defective Products] [hereinafter French Product Liability Act] (inserting art. 1386-11, §4, development risk defense, into the French Civil Code, bk. III, tit. IV(A), art. 1386); *id.* art. 13 (inserting art. 1386-12, exception to development risk defense, into the French Civil Code, bk. III, tit. IV(A), art. 1386). *See also* Green Paper, *supra* note 56, at 24 (suggesting France allowed development risk defense with exception of products derived from human body and those marketed before May 1998); PEARL, *supra* note 38, at 11 (noting France does not allow liability for development risks apart from products derived from human body).

62. On the Application of Directive 85/374 on Liability for Defective Products: Report from the Commission of the European Communities, COM(2000)893 final 7-8 [hereinafter Report].

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).

66. *See* Product Liability in the European Union: A Report for the European Commission, MARKT/2001/11/D, Feb. 2003, i [hereinafter Lovell's Study] (giving background information related to commission of study). *See also,* John Meltzer, *Reform of Product Liability in the EU: New Report Finds General Satisfaction,* 71 DEF. COUNS. J. 42, 42 (2004) (referring to Lovell's appointment by European Commission to study functioning of Directive in EC).

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.[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.[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.[71] The European Commission has undertaken a separate study to determine the economic impact of removing the development risk defense.[72]

B. *Implementation of the Directive and the Development Risks Option*

From the very beginning, there was a tension between the two institutions[73] responsible for drafting the Directive:[74] the European Commission,[75] which advocated strict liability for con-

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69. *See* Lovell's Study, *supra* note 66, at 34 (attributing increase in claims to consumer awareness of rights, consumer access to information and media activity with Directive playing smaller role); Meltzer, *supra* note 66, at 45-46 (observing that three major factors identified contributing to increase in claims are consumer awareness of rights, greater access to information and media activity, with Directive identified as major factor by 25% of participants).

70. *See* Lovell's Study, *supra* note 66, at 37 (noticing greater success in product liability claims, attributable to Directive); Meltzer, *supra* note 66, at 46 (stating 50% of participants thought product liability claims had been more successful).

71. *See* Lovell's Study, *supra* note 66, at 42-44 (explaining prevailing view was that Directive struck appropriate balance between consumer protection and protecting needs of producers or suppliers); Meltzer, *supra* note 66, at 48 (commenting on view of 66% of participants who thought Directive struck an appropriate balance).

72. *See* Lovell's Study, *supra* note 66, at vi (reporting separate study to determine economic impact of removing development risk defense).

73. *See* HANLON, *supra* note 10, at 24 (listing five Community institutions, which are European Commission, European Council of Ministers, European Court of Auditors, European Court of Justice, and European Parliament); VINCENZI & FAIRHURST, *supra* note 10, at 43 (describing five Community institutions).

74. *See* Culhane, *supra* note 25, at 28-29 (describing process of directive drafting, consulting and adoption). *See also* SARAH L. CROFT & BEATRICE HARICHAUX DE TOURDONNET, THE EUROPEAN PRODUCT LIABILITY DIRECTIVE IN PRACTICE, FOR THE DEFENSE 13 (2000) (describing roles of European Institutions).

75. *See* Directive, *supra* note 11, at pmbl. (identifying Article 100 of Treaty establishing European Economic Community, which specifies that "[t]he Council shall, acting unanimously on a proposal from the Commission and after consulting the European Parliament and the Economic and Social Committee, issue directives for the approximation of such laws," as the source of legislative power); Culhane, *supra* note 25, at 28 (remarking that European Commission of EC drafts proposals for directives); An-

sumer protection,[76] and the European Parliament,[77] which voiced its discomfort in imposing liability for risks that the manufacturer could not have known about.[78] In the end, a compromise was reached that provided the Article 7(e) "development risk" defense to the general rule of strict liability.[79] 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.[80]

In a community of fifteen countries with legal systems that reflect a diversity of culture,[81] an agreement was made to harmonize product liability law irrespective of the varying levels of consumer protection already established in each individual country.[82] Where the Member States have diverged is in their imple-

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dreas P. Reindl, *Consumer Protection and the Uniform Commercial Code: Consumer Contracts and European Community Law*, 75 WASH. U.L.Q. 627, 642-43(1997) (noting European Commission has exclusive right to propose Community acts).

76. *See* Stapleton, *Bugs in Products Liability*, *supra* note 34, at 1245 (reporting European Commission strongly preferred imposition of strict liability); The Right Honourable The Lord Griffiths, M.C. et al., *Developments in English Product Liability Law: A Comparison with the American System*, 62 TUL. L. REV. 353, 362-63 (stating European Commission favored strict liability for defective products); Reindl, *supra* note 75, at 644 (noting among Community institutions, European Parliament is probably most pro-consumers).

77. *See* Culhane, *supra* note 25, at 29 (noting European Council has power to adopt proposal into law but must consult with European Parliament before doing so); VINCENZI & FAIRHURST, *supra* note 10, at 79-80 (describing legislative procedure for policy areas relating to approximation of national laws). The European Parliament serves an advisory role to the Council of Ministers, which has ultimate authority to adopt the final version of the directive. *See id.*

78. *See* Culhane, *supra* note 25, at 31 (remarking that European Parliament was concerned about imposing liability for development risks); Stapleton, *Bugs in Products Liability*, *supra* note 34, at 1231 n.32 (citing European Parliament's concern about imposing liability for development risks).

79. *See* Culhane, *supra* note 25, at 31 (asserting industry-friendly compromise was reached by including development risk defense); Stapleton, *Bugs in Products Liability*, *supra* note 34, at 1248 (stating that purpose of allowing development risk defense, against wishes of European Commission, was to protect industry).

80. *See* Culhane, *supra* note 25, at 31 (citing development risk defense); Stapleton, *Bugs in Products Liability*, *supra* note 34, at 1248 (referring to development risk defense).

81. *See* Collette B. Cunningham, *In Defense of Member State Culture: The Unrealized Potential of Article 151(4) of the EC Treaty and the Consequences for EC Cultural Policy*, 34 CORNELL INT'L L.J. 119, 121 (2001) (noting fifteen Member States have distinct cultural identity); Charles H. Koch, Jr., *Envisioning a Global Legal Culture*, 25 MICH. J. INT'L L. 1, 18 (2003) (observing Europeans and their legal cultures are not homogeneous).

82. *See generally*, HODGES, *supra* note 17 (laying out product liability law in Member States before and after implementation of the Directive); HOFFMAN & HILL-ARNING,

mentation of the development risk defense.[83] Two countries, Finland and Luxembourg, have chosen not to implement the defense[84] while three countries, France, Spain and the United Kingdom have deviated from the rest of the Member States in their implementation of the defense.[85]

1. Finland

Finnish product liability law grew from the contractual relationship between seller and buyer.[86] Nordic countries like Finland adopted the *culpa* theory of contractual responsibility,

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supra note 17 (surveying Member States' product liability law before and after implementation of the Directive); KELLY & ATTREE, *supra* note 17 (comparing product liability law before and after implementation of Directive in Member States).

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 (BGB1.I S. 3018), zuletzt geändert durch Ges. v. 25. Februar 1998 (BGB1. 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).

86. *See* Consumer Protection Act 39/1978, ch. 5, § 1(1), *available at* http://www.finlex.fi/pdf/saadkaan/E9780038.PDF (last visited Apr. 12, 2004) (limiting provisions of chapter to sale of goods where seller is a business and buyer is consumer). *See also* HODGES, *supra* note 17, at 292 (observing product liability in Finland originated from sale of goods concepts applicable between seller and buyer).

which is liability based on negligence on the part of the seller.[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.[88] Finland implemented the Directive by adopting the Law of April 21, 1989 on the Civil Liability for Defective Products.[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.[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.[91] In the end, the development risk defense was not included.[92]

2. Luxembourg

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

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).

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).

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).

90. *See* HOWELLS, *supra* note 17, at 157 (describing arguments made by consumer movement).

91. *See id.* (outlining arguments made by consumer movement).

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).

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).

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.[95] The Directive was implemented in Luxembourg through the Act of April 21, 1989 on Civil Liability for Defective Products.[96] The development risk defense was excluded after some debate between the Judicial Commission of Luxembourg and the Luxembourg Chamber of Commerce.[97] 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.[98] The Luxembourg Parliament, fearful that the development risk defense would erode consumer protections,[99] excluded the defense.[100]

3. France

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

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(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 LUXEMBURG 210 (Michael Corkery trans., 1982) (noting Article 1382 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).

97. *See* Projet de Loi relatif à la responsabilité civile du fait des produits défectueux [Proposed law concerning the civil liability of manufacturers of defective products], Chambre des Députés, No. 3287, at 4-5 (Mar. 1, 1989) (Lux.) [hereinafter Luxembourg's Proposed Law] (outlining debate between Judicial Commission of Luxembourg and Luxembourg Chamber of Commerce). *See also* Linger, *supra* note 14, at 498-99 (describing positions of Judicial Commission and Chamber of Commerce).

98. *See* Luxembourg's Proposed Law, *supra* note 97, at 9-10 (arguing imposition of liability for development risk disincentivizes 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.[101] Exceeding even the early U.S. approach of *res ipsa loquitur*, the French *Cour de Cassation* established an irrebuttable presumption of manufacturer negligence.[102] The effects of the presumption were muted by French tort law, however, which did not consider buyers to be proper plaintiffs.[103] Tort actions could only be brought by non-purchasing third parties only;[104] buyers were required to sue under contract theory.[105] Under the Civil Code, warranty law applied to products cases[106] and was in fact more generous to injured plaintiffs than the U.S. Uniform Commercial Code.[107] 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.[108]

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).

103. *See* CODE CIVIL art. 1384 (2000 ed. Petits Codes Dalloz 2000) (Fr.) [hereinafter C. CIV.], *translated in*, THE CODE NAPOLEON 274-75 (Bryant Barrett trans. 1999). *See also* Culhane, *supra* note 25, at 21 (noting proper plaintiffs under tort sections do not include buyer, who must sue under contract law); Albanese & Del Duca, *supra* note 40, at 199 (stating injured non-purchaser must act in tort).

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.[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.[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.[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.[112] Additionally, there was at least some precedent for a development risk defense, France having allowed the defense for pharmaceuticals.[113] After much

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109. *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*, *supra* note 60 (stating French implementation of Directive had been stalled by disagreement over development risk defense).

110. *See* Linger, *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, *supra* note 17, at 102 (discussing Article 1641 which made sellers liable for hidden defects and stating undiscoverability of defect was not defense on general principles).

111. *See* Rothman & Finon, *Responsabilité du fait des Produits: Vers le Développement d'un Régime Défectueux*, 124 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, *supra* note 14, at 501-02 (citing commentators' concern that fear of liability will cause producers to adopt code of silence regarding defective products).

112. *See* Simon, Observations des Professionnels sur l'introduction en Droit Francais de la Directive Européenne la Responsabilité du Fait des Produits Défectueux [Professional Observations on the Introduction in French Law of the European Directive on the Responsibility of Defective Products], at 198 (reporting *Conseil National*'s concern that development risk defense would create competitive distortions in EU thereby undermining product liability law harmonization and encouraging forum shopping); Linger, *supra* note 14, at 502 (explaining *Conseil National*'s argument that optional development risks defense would cause competitive distortions among producers of EC and would undermine product liability law harmonization and encourage forum shopping by injured consumers).

113. *See* Hurd, *supra* note 27, at 61 (noting pre-Directive French law imposed liability for development risks with exception of pharmaceuticals); Anne E. Wells, *Regulating Experimental AIDS Drugs: A Comparison of the United States and France*, 13 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).

debate, France opted in on the development risk defense.[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.[115]

France finally incorporated the Directive into national law on May 19, 1998.[116] Although France conceded to the development risk defense, the controversy surrounding the defense did not subside.[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.[118] The develop-

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114. *See* French Product Liability Act, *supra* note 61, art. 12 (implementing development risk defense). *See also* Green Paper, *supra* note 56, at 34 (reporting France ultimately allowed development risk defense with exception of products derived from human body); PEARL, *supra* note 38, at 11 (stating France does not allow liability for development risks apart from products derived from human body).

115. *See* HODGES, *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, *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).

116. French Product Liability Act, *supra* note 61. *See Defective Products: Proceedings Against Paris and Athens for Poor Transposition of EU Directive*, EUR. REP., Jan. 19, 2000, at 2467 [hereinafter EUROPEAN REPORT] (noting date Directive was transposed into national law in France). *See also* Opinion of Advocate General Geelhoed, Commission of the European Communities v. French Republic, Case C-52/00, [2001] E.C.R. _, at ¶ 7 (identifying French legislation transposing Directive into national law).

117. *See also* Opinion of Advocate General Geelhoed, *French Republic*, [2001] E.C.R. _ (representing debate between Commission and French Republic on how to apply development risk defense).

118. *See* French Product Liability Act, *supra* note 61, art. 13 (inserting Article 1386-12 into French Civil Code). Article 1386-12, ¶ 2 states:

> Le producteur ne peut invoquer les causes d'exonération prévues aux 4° et 5° 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 year after putting into circulation of the product, it did not make the provisions suitable to prevent the detrimental consequences of them].

Id. 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).

mental risk defense, however, as defined by the Directive, is not a conditional defense.[119] 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.[120]

The French Government justified its actions on three grounds.[121] It argued first that the European Commission is itself considering an amendment to exclude the development risk defense.[122] Second, the Directive gives Member States a certain amount of flexibility in the implementation of the optional provision.[123] Third, the obligation imposed by Article 1386-12 is explicitly laid down in another directive, the General Product

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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).

121. *See* Opinion of Advocate General Geelhoed, *French Republic*, [2001] E.C.R. _ at ¶ 83 (outlining French Republic's arguments).

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,[124] which imposed an obligation on producers to monitor products which are sold.[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.[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.[127] Advocate General ("AG") Geelhoed[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

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124. Council Directive No. 92/59, O.J. L 228/24 at 24-32 (1992). More recently, a newly revised Directive on General Product Safety ("revised GPS") was adopted, to be transposed into national legislation by January 2004. Council Directive No. 2001/95, O.J. L 11/4, at 4-17 (2002). The revised GPS Directive does not cover food safety, which is now regulated by Council Regulation No. 178/2002, O.J. L 31/1, at 1-24 (2002). The revised GPS better defines appropriate safety specifications corresponding to the concept of "safe" products. For information on the revised GPS Directive, see http://europa.eu.int/comm/consumers/cons_safe/prod_safe/gpsd/index_en.htm.

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.

Id.

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).

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

128. *See* HANLON, *supra* note 10, at 58 (observing European Court of Justice is made up of fifteen judges and nine Advocate Generals); 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* HANLON, *supra* note 10, at 59 (noting one AG is assigned to each case); 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* HANLON, *supra* note 10, at 59-60 (describing advisory role of AG in Court of Justice); 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."[129] As a result, the AG concluded that the French Republic failed to comply fully with the Directive.[130] Pursuant to the AG's recommendation,[131] the European Court of Justice ruled that France had failed to fulfill its obligations under the Directive.[132] As of July 2003, France had yet to comply with the European Court of Justice's judgment of April 2002.[133]

4. Spain

Spanish contract-based product liability allowed two distinct rights of action, under the law of sales and the *obligations theory*.[134] The *obligations theory*, as described in Article 1101 of the Spanish Civil Code, made a seller liable for damages and harms caused through negligence.[135] Article 1484 further held sellers

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129. Opinion of Advocate General Geelhoed, *French Republic*, [2001] E.C.R. _ at ¶ 87 (finding French government's defense unconvincing).

130. *See id.* at ¶¶ 86, 89 (reporting AG's conclusion that France failed to comply with Directive). *See also Internal Market: Commission Moves Against 13 Member States for Failure to Implement EU Legislation*, Commission Press Release, IP/03/1005, 4 (July 14, 2003), *available at* http://europa.eu.int/en/comm/spp/rapid.html [hereinafter *Internal Market* (July 14, 2003)] (mentioning European Court of Justice found French Product Liability Act did not conform to Directive); *Internal Market: Commission protects the free movement of goods and services in France, Italy and the Netherlands*, Commission Press Release, IP/03/581 2 (Apr. 28, 2003), *available at* http://europa.eu.int/en/comm/spp/rapid.html [hereinafter *Internal Market* (Apr. 28, 2003)] (declaring French Product Liability Act provisions were incompatible with Directive).

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* note 10, at 60 (discussing Court of First Instance); VINCENZI & FAIRHURST, *supra* note 10, at 120 (mentioning creation of Court of First Instance).

132. *See* Judgment of the Court of Apr. 25 2002, *Commission v. French Republic*, [2002] E.C.R. I-3827, at ¶ 49 (holding France failed to fulfill its obligation under Directive).

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.[136] Under the *obligations theory*, sellers were liable for injuries foreseeable at the time the obligation arose, thereby excluding liability arising from development risks.[137]

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

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of their obligations, incur . . . negligence . . . are liable for the resulting damages"). *See also* Ansaldi, *supra* note 54, at 378-79 (describing *obligations theory* of contracts).

136. *See* C.C., *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"). *See also* Ansaldi, *supra* note 54, at 379 (explaining sellers are responsible for latent defects under law of sales); HODGES, *supra* note 17, at 585 (citing Article 1484 as making seller liable for hidden defects in good being sold).

137. *See* Ansaldi, *supra* note 54, at 380 (noting foreseeability in *obligations theory* excludes liability from development risks); GERD BRUGGEMANN, 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).

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

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

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

141. *See* Culhane, *supra* note 25, at 21 (asserting *Cour de Cassation* established irrebuttable presumption of manufacturer negligence); HODGES, *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).

142. *See, e.g.*, Judgment of the Supreme Court of June 22, 1931 (noting presumption of negligence in extra-contractual liability). *See also* Ramon Mullerat & Sonia Cortes, *Spain*, *in* EUROPEAN PRODUCTS LIABILITY 339, 348 (Patrick Kelly & Rebecca Attree eds., 1992) (reporting presumption of negligence by producer).

143. *See* Ansaldi, *supra* note 54, at 382 (noting Spanish courts inverted burden of proof, requiring defendant to prove diligence); HODGES, *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.[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.[145] The GAC codified existing Spanish jurisprudence, like the rebuttable presumption of fault and set up a strict liability regime in Spain.[146] Everyone in the production and distribution chain was held strictly liable.[147] The GAC was severely criticized for sloppy draftsmanship but nevertheless signified a major advance for Spanish consumers.[148]

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

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).

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 Steeped 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 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).

146. *See* Ansaldi, *supra* note 54, at 387-88 (discussing Article 26 of General Law for the Defense of Consumers and Users ("GAC")); Paloma Peman Domecq, *Products Liability in Spain*, 15 COMP. L.Y.B. INT'L BUS. 137, 140 (1993) (noting if defendant proves absence of negligence, he is exonerated from liability).

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).

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).

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).

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,

fense was, of course, in contention.[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.[152] In the end, Spain decided to allow a partial defense.[153] The SPLA allows for a development risk defense[154] except as to "pharmaceutical products, foodstuffs or food products intended for human consumption."[155]

5. United Kingdom

In the United Kingdom, the duty to non-consumers was recognized when the rule of privity was abandoned by *Donoghue v. Stevenson*.[156] *Donoghue* allowed a fault-based cause of action for

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supra note 38, at 11 (noting date of adoption of Spanish national product liability law). For detailed information on the Spanish Products Liability Act, see Antonio J. Vela Sanchez, *Products Liability in Spain*, 32 TEX. TECH. L. REV. 979 (2001) (reviewing provisions of Spanish Products Liability Act of 1994).

151. *See* Ansaldi, *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, *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).

152. *See* Ansaldi, *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). *See generally*, I. Vega, *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).

153. *See* Ansaldi, *supra* note 54, at 400 (remarking pharmaceutical products and food products are excluded from development risk defense); HODGES, *supra* note 17, at 591 (observing draft SPLA included defense, but not for pharmaceuticals or food products).

154. *See* Spanish Product Liability Act, *supra* note 54, art. 6(1)(e) (outlining development risk defense).

155. *See* Spanish Products Liability Act, *supra* note 54, art. 6(3) (stating exceptions to development risk defense). *See also* Ansaldi, *supra* note 54, at 428-29 (noting pharmaceutical products and food products are excluded from development risk defense); HODGES, *supra* note 17, at 591 (noting draft SPLA included defense, but not for pharmaceuticals or food products).

156. *See* Donoghue v. Stevenson, [1932] A.C. 532, [1932] All ER Rep 1 (abandoning rule of privity). *See also* Abed Awad, *The Concept of Defect in American and English Products Liability Discourse: Despite Strict Liability Linguistics, Negligence is Back With a Vengeance!*, 10 PACE INT'L L. REV. 275, 283 (1998) (citing *Donoghue*, where Court overruled *Winterbottom*'s privity rule); Stapleton, *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).

injuries caused by defective products.[157] Actions for negligence were not limited to those in privity to the defendant.[158] Negligence-based product liability law in England developed into strict liability through legislative action with the Sale of Goods Act of 1979.[159] Thus, starting from 1979, consumers had the option to bring an action under statutorily created warranties.[160] Such actions were advantageous in that the warranties of quality and fitness for purpose were implied terms to contracts[161] and recovery was allowed for both physical and pure economic loss caused by breach of warranty.[162] Contract claims however, remained limited to those in privity with the seller.[163]

The United Kingdom implemented the Directive through the Consumer Protection Act, which came into force on March 1, 1988.[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.[165] With

157. *See* Awad, *supra* note 156, at 284 (stating *Donoghue* created negligence cause of action for defective products); Stapleton, *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, *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).

159. *See* Awad, *supra* note 156, at 284-85 (noting England relied on legislative evolution toward strict liability, enacting consumer protection laws like the Sale of Goods Act); Stapleton, *Myths of Reform*, *supra* note 13, at 48 (referring to Sale of Goods Warranties as providing strict liability claims for consumers).

160. *See* Stapleton, *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, *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, *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, *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, *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.[166] 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.[167] 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.[168]

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)*").[169] The controver-

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to sign Directive only with provision in place); Stapleton, *Bugs in Products Liability*, *supra* note 34, at 1232 (noting that development risk defense was compromise demanded by Thatcher administration).

166. *See* Hodges, *Unanswered Questions*, *supra* note 49, at 563 (noting United Kingdom was only Member State not to adopt wording of Directive verbatim); Stapleton, *Myths of Reform*, *supra* note 13, at 57 (noting all other Member States implementing development defense merely reproduced the wording of Directive). *But see* Hurd, *supra* note 27, at 53 (stating Italy implemented development risk defense in a manner more generous to producers than that of Directive and European Commission has brought an action against Italy based on language of development risk defense); Patrick Thieffry et al., *Strict Product Liability in The EEC: Implementation, Practice and Impact on U.S. Manufacturers of Directive 85/374*, 25 TORT & INS. L.J. 65, 79 (1989) (noting European Commission found Italy's wording of development risk defense too general and has decide to bring proceedings against Italy). However, subsequent publications make no mention of a proceeding against Italy. *See* Patrick E. Thieffry, *EEC Directive 85/374 on Liability for Defective Products: Implementation and Practice* 35-36 (PLI Litig. & Admin. Practice Course Handbook Series No. 371, 1989) (discussing Italy's implementation of Directive); Richard H. Dreyfuss, *The Italian Law on Strict Products Liability*, 17 N.Y.L. SCH. J. INT'L & COMP. L. 37, 72-73 (1997) (discussing Italy's decision to excluded liability for development risks).

167. *See* Consumer Protection Act, *supra* note 53, at ch. 43, pt. 1, § 4(1)(e) (outlining UK's development risk defense). *See also* Stapleton, *Myths of Reform*, *supra* note 13, at 57 (noting producer-friendly construction of UK's development risk defense).

168. *See* Commission of the European Communities v. United Kingdom of Great Britain and Northern Ireland, Case C-300/95, [1997] 3 C.M.L.R. 936; Opinion of Advocate General Tesauro, Commission of the European Communities v. United Kingdom of Great Britain and Northern Ireland, Case C-300/95, [1997] E.C.R. I-2649, [1997] 3 C.M.L.R. 923 (summarizing European Commission's action against United Kingdom for failure to implement Directive).

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.[170] The EC, having based the Directive on Section 402A did not escape this debate.[171] Commentators argue that absolving manufacturers of liability associated with unknowable or unavoidable risks muddles a strict liability system with exceptions.[172] Others argue that it is inherently unfair to hold manufactures liable for risks over which they have no control.[173] 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.[174]

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(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.

170. *See* Garey B. Spradley, *Defensive Use of State of the Art Evidence in Strict Products Liability*, 67 MINN. L. REV. 343, 348 (1982) (commenting on tension between negligence and strict liability theory and role of state-of-the-art); Gary C. Robb, *A Practical Approach to Use of State of the Art Evidence in Strict Products Liability Cases*, 77 NW. U. L. REV. 1, 10 (1982) (characterizing relationship between state-of-the-art evidence and strict liability); Ellen Wertheimer, *Unknowable Dangers and the Death of Strict Products Liability; The Empire Strikes Back*, 60 U. CIN. L. REV. 1183, 1206 (1992) (describing role of state-of-the-art in differentiating negligence based liability from strict product liability).

171. *See* Hodges, *Unanswered Questions*, *supra* note 49, at 569 (discussing interpretation of development risk defense in United Kingdom under Directive); Stapleton, *Myths of Reform*, *supra* note 13, at 67 (remarking Directive provides pockets of strict liability but leaves design defect cases under fault-based liability); Mark Mildred & Geraint Howells, *Comment on 'Development Risks: Unanswered Questions'*, 61 MODERN L. REV. 570, 573 (1998) (arguing for removal of development risk defense).

172. *See* Howells & Mildred, *supra* note 39, at 987 (pointing out that defense runs counter to rationale of strict liability); Mildred & Howells, *supra* note 171, at 573 (advocating removal of development risk defense).

173. *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 for development risk defense interpretation).

174. *Marshall S. Shapo, Comparing Products Liability: Concepts in European and American Law*, 26 CORNELL INT'L L.J. 279, 302 (1993) (commenting on state-of-the-art contro-

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.[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.[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.[177] This conflation of state-of-the-art with "development risks," oversimplifies the relevant concepts.[178] State-of-the-art, as it is used in U.S. product liability law, can mean anything from industry custom to technological feasibility.[179] "Development risk" in the EC has been defined more narrowly.[180] Another commentator

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versy in United States and development risk controversy in Europe); *See* Howells & Mildred, *supra* note 39, at 998, 1025 (comparing state-of-the-art considerations in United States and development risk defense in Europe).

175. *See* Directive, *supra* note 11, art. 7(e) (establishing development risk defense).

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.

177. *See* Linger, *supra* note 14, at 488 (using "state-of-the-art" and "development risks defense" synonymously).

178. *See* Frank J. Vandall, *State-of-the-art, Custom, and Reasonable Alternative Design*, 28 SUFFOLK U. L. REV. 1193, 1200-03 (1994) (noting varying definitions of state-of-the-art); Opinion of Advocate General Tesauro, *United Kingdom*, [1997] E.C.R. at ¶¶ 21-24 (defining development risk defense as being determined by most advanced state of scientific knowledge and accessibility of that knowledge).

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).

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 circulation[182] and the Article 6(2) subsequent remedial measures caveat[183] 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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to disparage the effort. They are no where near as great as the variations that exist in United States product liability law.

Hurd, *supra* note 27, at 68 (pointing out that variations in Member States' product liability laws are not as great as variations in U.S. product liability law).

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. 239, 256 (1996) (stating that cases presenting issues of unknowable risks outline scope of development risk defense).

185. *See* John H. Chun, *The New Citadel: A Reasonably Designed Product Liability Restatement*, 79 CORNELL L. REV. 1654, 1654 (1994) (noting Section 402A is most frequently cited provision of *Restatement (Second)*); Henry J. Reske, *Experts Tackle Torts Restatement: Product Liability Gets First Review; Design Defects and Warnings At Issue*, 78 A.B.A. J. 18, 18 (Aug. 1992) (remarking Section 402A of *Restatement (Second)* is cited more frequently by courts than any other part of any ALI restatement).

186. *See* John F. Vargo, *The Emperor's New Clothes: The American Law Institute Adorns a "New Cloth" for Section 402A Product Liability Design Defects—A Survey of The States Reveals a Different Weave*, 26 U. MEM. L. REV. 493, 507 (1996) (stating almost every jurisdiction immediately adopted Section 402A); David G. Owen, *The Fault Pit*, 26 GA. L. REV. 703,

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

a. Design Defectiveness

Section 402A is silent when it comes to defining design defectiveness,[190] but *comment i* suggests that 402A applies when the product defect makes it "unreasonably" dangerous to the consumer.[191] Relying on the reference to the consumer as the judge of defectiveness in *comment i*, courts devised the "consumer expectation test" to evaluate design defectiveness.[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.[193] Over the years, courts have formulated other ap-

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714 (1992) (noting "explosive spread" of strict product liability following introduction of Section 402A of *Restatement (Second)*); Chun, *supra* note 185, at 1657 (reporting Section 402A of *Restatement (Second)* is nearly universal rule).

187. *See* Theodore S. Jankowski, *Focusing on Quality and Risk: The Central Role of Reasonable Alternatives in Evaluating Design and Warning Decisions*, 36 S. TEX. L. REV. 283, 309 (1995) (observing confusion on meaning of defect following emergence of Section 402A of *Restatement (Second)*); Wertheimer, *supra* note 170, at 1191 (noting focus of debate involving strict product liability has been on definition of defect).

188. *See* Jankowski, *supra* note 187, at 309-10 (describing emergence of three categories of product defect); John W. Wade, *On The Effect in Product Liability of Knowledge Unavailable Prior to Marketing*, 58 N.Y.U. L. REV. 734, 740 (1983) (stating three ways product defect can become actionable).

189. *See* Douglas A. Kysar, *The Expectations of Consumers*, 103 COLUM. L. REV. 1700, 1709 (2003) (noting task of determining proper test for design defectiveness has been focus of product liability); David G. Owen, *Defectiveness Restated: Exploding the "Strict" Products Liability Myth*, 1996 U. ILL. L. REV. 743, 753 (1996) (asserting most vexing problem in product liability law is determination of proper basis of liability for dangers in design).

190. *See* Kysar, *supra* note 189, at 1711 (pointing out Section 402A does not define defectiveness); Joseph W. Little, *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).

191. *See* RESTATEMENT (SECOND) § 402A, cmt. i (1965).

192. *See* Kysar, *supra* note 189, at 1712-13 (discussing *comment i* and consumer expectation test); Jankowski, *supra* note 187 at 314-18 (outlining consumer expectation approach).

193. *See* HENDERSON & TWERSKI, *supra* note 7, at 492 (observing some commentators and courts denounce risk-utility test which sounds very much like negligence and

proaches to determining the adequacy of product design, most notably the risk-utility test.[194] The risk-utility test determines the reasonableness of the manufacturer's design decision in balancing the potential risks involved and the cost to the manufacture of preventing injuries,[195] a concept very much rooted in negligence theory.[196]

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.[197] 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.[198] First used in a 1956 Illinois case involving an allegedly negligently designed door,[199] state-of-the-art was never clearly defined, leading to the present

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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).

196. *See* Chun, *supra* note 185, at 1658-59 (noting risk-utility approach derives from negligence standard); Patrick Lavelle, *Crashing Into Proof of a Reasonable Alternative Design: The Fallacy of the Restatement (Third) of Torts: Products Liability*, 38 DUQ. L. REV. 1059, 1061 (2000) (stating reasonable alternative design requirement "injects negligence principles").

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.[200]

At least three discrete uses of the term state-of-the-art have appeared since its introduction in the mid-50's:[201] (1) as customary industry practices;[202] (2) as governmental standards;[203] and (3) as the practicality or feasibility of a design.[204] A fifty-state survey of the admissibility of state-of-the-art evidence is beyond the scope of this Note.[205] 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.[206]

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200. *See* Robb, *supra* note 170, at 5 (noting confusion that exists among courts in applying state-of-the-art concept); Vandall, *supra* note 178, at 1193 (remarking there is no widely accepted definition of state-of-the-art).

201. *See* Vandall, *supra* note 178, at 1193, 1200-03 (discussing various usages of state-of-the-art); Spradley, *supra* note 170, at 344-47 (summarizing common use of state-of-the-art); Robb, *supra* note 170, at 4-5 (noting many different definitions of state-of-the-art).

202. *See* Wertheimer, *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, *supra* note 170, at 355-63 (raising argument against admitting state-of-the-art evidence when it is defined as industry practice); Robb, *supra* note 170, at 16 (noting few courts treat state-of-the-art as industry standards).

203. *See* Vandall, *supra* note 178, at 1200-01 (discussing use of government standards as state-of-the-art); Spradley, *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, *supra* note 178, at 1200-01 (discussing Wilson v. Piper Aircraft Corp., 577 P.2d 1322 (1978)); Spradley, *supra* note 170, at 367 (stating governmental standards define minimum product design quality and conditions of distribution).

204. *See* Vandall, *supra* note 178, at 1201-03 (discussing role of state-of-the-art in proving reasonable alternative design); Robb, *supra* note 170, at 17-18 (pointing out use of state-of-the-art to set up parameters of feasibility).

205. Several useful compilations have been assembled by others. *See generally* Vargo, *supra* note 186 (providing fifty state survey on design defect cases including treatment of state-of-the-art evidence); 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); PRODUCTS LIABILITY DEFENSES: A STATE-BY-STATE COMPENDIUM (Davidson Ream ed., 2001) (1992) (giving information on possible defenses to product liability in each state).

206. *See* Spradley, *supra* note 170, at 359 (noting courts have considered industry practice probative in determining existence of design defect); James Boyd & Daniel E. Ingeberman, *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).

Alaska and Texas have taken this minority position of treating industry practice as state-of-the-art evidence.[207] The Supreme Court of Alaska discussed state-of-the-art and industry custom in *Keogh v. W.R. Grasle, Inc.*[208] as if they were the same, noting that "state-of-the-art or industry custom evidence"[209] was not dispositive in determining whether there is any liability but that the jury was allowed to consider such evidence.[210] Additionally, the Supreme Court of Texas' opinion in *Bailey v. Boatland of Houston, Inc.*[211] is frequently cited on the question of whether industry standards should be admitted as state-of-the-art evidence.[212] Samuel Bailey was thrown out of the boat he was operating and killed by the propeller when the boat circled back towards him.[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.[214] The defendant introduced evidence that the use of kill switches were known, but not used in the industry.[215] Although the majority opinion in *Boatland* distinguished indus-

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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).

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

209. *Id.* at 1349 (indicating Court's synonymous treatment of the two concepts).

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.

Id. at 1349 n.10. However, in *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).

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

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

213. *See 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).

214. *See id.* (explaining Bailey's wife and children sued Boatland for not including kill switch, which they claim makes boat defectively designed).

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,[216] Justice Campbell argued in a dissenting opinion that practically speaking, the majority made no such distinction.[217] 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."[218]

The most convincing argument against allowing consideration of industry standards is attributed to Judge Learned Hand in *The T.J. Hooper*.[219] 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."[220] As suggested by one commentator, admitting industry custom as state-of-the-art evidence would eviscerate the incentive for manufacturers to adopt safer practices.[221]

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.[222] 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.[223] While some jurisdictions allow defendants to submit state-of-the-art evidence as an affirmative defense to liability,[224] other jurisdictions grant a rebuttable presumption in favor of non-defectiveness.[225] 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.[226]

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.[227] The battle between strict liability and negligence regimes reflects a debate over the apportionment of risk.[228] Fact patterns which deal with unknown or una-

223. *See* PRODUCTS LIABILITY PRACTICE GUIDE pt. I, ch. 15, § 15.08 (2003) (remarking state-of-the-art concept encompasses practical considerations as well as technical possibility); HENDERSON & TWERSKI, *supra* note 7, at 594 (noting state-of-the-art concept evaluates safety features available at time of distribution taking into consideration cost effectiveness).

224. *See, e.g.*, Iowa Code § 668.12 (1987); 2A N.J. Stat. Ann. § 58C-3(a)(1); N.H. Rev. Stat. Ann. § 507:8-g. *See generally* MADDEN & OWEN § 10:5, *supra* note 222, at n.44 (providing examples of states that allow state-of-the-art evidence in as complete defense to liability).

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).

228. *See* Howells & Mildred, *supra* note 39, at 998 (noting general philosophy of risk-spreading is underpinning of strict liability). *See generally* Calabresi & Hirschoff, *supra* note 15, at 1055 (discussing rationale of strict liability in torts).

voidable risks[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.[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,[231] and is therefore directly relevant to whether a risk was unknown or unavoidable.[232]

The discussion of unavoidable risks implicates *comment k* of Section 402A,[233] which has been referred to by some as the unavoidably unsafe product liability defense.[234] *Comment 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.[235] The majority of jurisdictions have decided to follow *comment k* for unavoidably unsafe prod-

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 risks are those that were known, but could not be prevented.

230. *See* Jane Stapleton, *International Torts: A Comparative Study: Restatement (Third) of Torts: Products Liability, an Anglo-Australian Perspective*, 39 WASHBURN L.J. 363, 368 (2000) [hereinafter Stapleton, *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).

231. *See* Spradley, *supra* note 170, at 379 (discussing limitations on scientific and technological knowledge); Andrew T. Berry, *Beshada v. Johns-Manville Products Corp.: Revolution-or Aberration-in Products Liability Law*, 52 FORDHAM L. REV. 786, 803 (1984) (noting scientific limitations in manufacturing defect cases and inadequacy of scientific knowledge for design defect cases).

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).

233. RESTATEMENT (SECOND) §402A, cmt. k (1965). *Comment k* states that "a product, properly prepared, and accompanied by proper directions and warning, is not defective." *Id.*

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

235. *See* Brown v. Superior Court (Abbott Laboratories), 751 P.2d 470, 477 (1988) (holding appropriate test for determining responsibility for defectively designed drug is *comment k* and not strict liability); George H. King, *A Prescription for Applying Strict Liability: Not All Drugs Deserve Comment K Immunization, Brown v. Superior Court, 44 Cal.3d 1049, 751 P.2d 470, 245 Cal.Rptr. 412 (1988)*, 21 ARIZ. ST. L.J. 809, 812 (1989) (noting ALI's refusal to apply strict liability to unavoidably unsafe products).

ucts.[236] The question that remained was whether liability should be imposed for products found to be defective because of unknowable risks.[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.[238] They emphasize that the basic premise of imposition of liability without fault is to relieve plaintiffs of the burden of proving negligence.[239] As Justice Traynor argued in *Escola v. Coca Cola Bottling Co. of Fresno*,[240] the manufacturer is in the better position to identify the cause of the defect.[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.[242] From a policy perspective, commentators have argued that strict liability will minimize future accidents and distribute the cost of compensating plaintiffs throughout society.[243] Accident minimization is achieved through deterrence, by motivating manufac-

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).

237. *See* Schwartz, *supra* note 15, at 654-55 (discussing case law dealing with unknowable risks); Richard C. Ausness, *Unavoidably Unsafe Products and Strict Products Liability: What Liability Rule Should be Applied to the Seller of Pharmaceutical Products?*, 78 KY. L.J. 705, 740-41 (1990) (remarking *comment k* does not cover scientifically unknowable risks).

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).

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).

240. 150 P.2d 436 (Cal. 1944).

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).

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).

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.[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.[245]

Very few courts have been adamant about not allowing state-of-the-art evidence.[246] Wisconsin stands lonely, if not alone, in its refusal to consider state-of-the-art.[247] The admissibility of state-of-the-art evidence in Wisconsin was decided in *Green v. Smith & Nephew AHP, Inc.*[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.[249] Green argued that the gloves were defectively designed because they contained excessive levels of allergy-causing latex proteins.[250] Green also asserted that the cornstarch used to powder the gloves increased the possibility

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minimization as rationales for imposing strict liability); Wertheimer, *supra* note 170, at 1185-91 (describing economic reasons for imposing strict liability).

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).

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

246. *See generally* Vargo, *supra* note 186 (providing fifty state survey on design defect cases including treatment of state-of-the-art evidence); THE STATE OF THE ART DEFENSE, *supra* note 205 (outlining information on possible defenses to product liability in each state); PRODUCTS LIABILITY DEFENSES, *supra* note 205 (giving information on possible defenses to product liability in each state).

247. *See* Green v. Smith & Nephew AHP, Inc., 629 N.W.2d 727, 735-36 (Wis. 2001) (holding manufacturer responsible for injuries caused by products regardless of whether he had or could have had knowledge of potential danger).

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

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, *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).

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.[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.[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.[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.[254] The defendant, S & N appealed, arguing that imposing liability for unknown defects transformed strict liability to absolute liability.[255] To avoid absolute liability, an element of foreseeability must be included in product liability law.[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.[257]

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

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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).

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).

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).

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).

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).

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

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.[258] In line with arguments made by S & N in the Wisconsin latex 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.[259] 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."[260] Proponents of strict liability argue that strict liability is not absolute liability.[261] Plaintiffs still have to prove the basic elements of a product liability case — causation, defect and injury.[262] Courts that have allowed state-of-the-art evidence find such evidence relevant to the issue of design defectiveness.[263]

The rationale behind imposing no-fault strict liability has been challenged as well.[264] Opponents of strict liability argue that for unknowable risks, the burden of proof rationale is not as

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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.[265] Similarly, the loss-spreading rationale does not seem to apply to unknowable risks, which are speculative at best.[266] Manufacturers cannot estimate the amount of loss or how often it may occur in order to spread the cost.[267] 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.[268] 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.[269] Furthermore, even large manufacturers have limited resources.[270] 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-

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265. *See* Ausness, *supra* note 237, at 744 (arguing that burden of proof rationale does not support imposition of strict liability because manufacturers lack control over scientifically unknowable risks of products). *See also* Christoph Ann, *Innovators in the Crossfire: A Policy Sketch for Unknowable Risks in European and United States Product Liability Law*, 10 TUL. EURO. CIV. L.F. 173, 182 (1995) (pointing out distortions in risk assessment for innovator liability due to lack of information).

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).

ket.[271] In fact, such liability will discourage manufacturers from marketing new products with unknown risks thereby reducing consumer choice by making lower priced product unavailable.[272]

2. Direction of the *Restatement (Third)*

In March 1992, the American Law Institute announced its intentions to revise Section 402A.[273] Of particular interest was the future development of strict product liability in design defect cases.[274] More than five years later, on May 20, 1997, the final draft of the *Restatement (Third)* was adopted.[275] Significantly, the *Restatement (Third)* adopted the risk-utility analysis for design defectiveness[276] and relegated the consumer expectation test to *res ipsa*-type defect cases.[277] Section 2(b) of *Restatement (Third)* defines design defectiveness in terms of the foreseeable risks of harm and a reasonable alternative design,[278] essentially adopting

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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).

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).

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).

274. *See* Lavelle, *supra* note 196, at 1060 (noting applicability of strict liability in design defect cases was principle point of contention); James A. Henderson, Jr. & Aaron D. Twerski, *Symposium on the American Law Institute: Process, Partisanship, and the Restatements of Law: The Politics of the Products Liability Restatement,* 26 HOFSTRA L. REV. 667, 694-95 (1998) (outlining debate over issue of defective design).

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).

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).

277. *See* Henderson & Twerski, *supra* note 274, at 678 (asserting consumer expectation test is recognized for *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 *res ipsa* products cases where consumer expectations may still be used).

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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the product could have been reduced or avoided by the adoption of a reasonable alternative design by the seller or other distributor, or a predecessor in the commercial chain of distribution, and the omission of the alternative design renders the product not reasonably safe.

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.[284] 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.[285] 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.[286]

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.[287] They particularly criticized Europe for following outdated 402A.[288] While the EC crafted its Directive in a manner reflecting lessons learned from three decades of product liability law in the United States,[289] it followed outdated 1960s U.S. rhetoric of strict liability.[290] As an example of the backwardness of the EC Directive, Professors Henderson & Twerski cite the language of

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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*, LOVELLS NEWSLETTER, Sept. 2003, at 8, *available at* http://www.lovells.com/control/PublicationControl/pubId/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.[291] They assert that although risks may be discovered, design defects require a value judgment, a risk-utility judgment.[292] Thus, the reference to "discovering the defect"[293] 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.[294]

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.[295] As mentioned above, although the United Kingdom implemented the Directive through the Act, its wording deviated from the original text of the Directive.[296] 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.[297]

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).

295. *See* Christopher Newdick, *The Development Risk Defense of the Consumer Protection Act 1987*, 47 CAMBRIDGE L.J. 455 (1988). *See also* Jane Stapleton, *Products Liability Reform – Real or Illusory?*, 6 OXFORD J. LEGAL STUD. 392, 417-19 (1986) (addressing issues with interpretation of development risk defense but in context of Directive rather than UK implementation of defense).

296. *See* Stapleton, *Myths of Reform*, *supra* note 13, 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:

> [I]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.[298] Instead, courts would rely on defendant's experts, in essence creating a strong presumption in favor of the defense.[299] Newdick also outlined a hypothetical situation where a plaintiff suing pharmaceutical Company X finds a confidential, internal memorandum from Company Y, disclosing the existence of the defect in the drug product of Company X.[300] Company Y is in an unrelated industry which by happenstance was using the same compound as Company X.[301] 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.[302]

Newdick goes on to define the scope of the development risk defense by outlining the boundaries of scientific and technical knowledge.[303] He first differentiated between the lack of

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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. (emphasis added). 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.[304] Newdick used refrigerator design as an example of general knowledge.[305] 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.[306] 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.[307] 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.[308] 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.[309] 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.[310]

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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.[311] The European Commission had corresponded with the United Kingdom for six years to no avail and finally brought action for infringements under Article 169[312] of the EC Treaty.[313] Under Article 169, the European Commission had the burden of proving infringement.[314]

The European Commission submitted that the development risk defense provided for in Section 4(1)(e) of the Act[315] imposed a lighter burden of proof than that imposed by the Directive.[316] Specifically, the Directive allowed the defense only if it was impossible to discover the defect given the state of scien-

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311. *See* Commission of the European Communities v. United Kingdom of Great Britain and Northern Ireland, Case C-300/95, [1997] 3 C.M.L.R. 936; Opinion of Advocate General Tesauro, Commission of the European Communities v. United Kingdom of Great Britain and Northern Ireland, Case C-300/95, [1997] E.C.R. I-2649, [1997] 3 C.M.L.R. 923.

312. Consolidated version of the Treaty establishing the European Community, art. 226, O.J. C 325/33, at 125 (2002), 37 I.L.M. 79, at 125 (ex Article 169), *incorporating changes made by* Treaty of Nice amending the Treaty on European Union, the Treaties establishing the European Communities and certain related acts, Feb. 26, 2001, O.J. C 80/1 (2001) (amending Treaty on European Union ("TEU"), Treaty establishing the EC ("EC Treaty"), Treaty establishing the ECSC, and Treaty establishing the Euratom and renumbering articles of TEU and EC Treaty). An infringement action under Article 226 (ex Article 169) against a Member State is for failing to fulfill its obligation under the Directive and under the EC Treaty by failing to take all of the measures necessary to implement a directive. *See* PEARL, *supra* note 38, at 19 (noting European Commission' burden under Article 226 (ex Article 169); HANLON, *supra* note 10, at 131 (stating in Article 226 (ex Article 226) actions, European Commission bears burden of proof).

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)).

315. Consumer Protection Act, *supra* note 53, § 4(1)(e).

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.[317] Thus, the European Commission argued that the United Kingdom implemented a subjective test, whereas the Directive required an objective one.[318]

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.[319] 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.[320] 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-

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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.[321]

The Opinion of the AG sought to balance strict liability and the fair apportionment of risk between the injured person and the producer.[322] AG Tesauro recommended that liability should depend on: (1) the state of scientific knowledge; and (2) the accessibility of that knowledge.[323] 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.[324] The harshness of this definition was tempered by considerations of the accessibility of the information, assessing the opportunity of the information to circulate.[325]

Ultimately, AG Tesauro based his opinion on procedural rather then substantive grounds.[326] 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-

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321. *See* Opinion of Advocate General Tesauro, *United Kingdom*, [1997] E.C.R. at ¶ 10, [1997] 3 C.M.L.R. 928, at ¶ 10 (citing Directive's objective of fair apportionment of risk). *See also* PEARL, *supra* note 38, at 20 (noting United Kingdom's argument that objectively verifiable standard is necessary for defense to provide fair apportionment of risk set out in seventh recital of Directive).

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 advance 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).

326. *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 (deciding that there was no clear conflict between Section 4(1)(e) of Consumer Protection Act and Article 7(e) of Directive).

sion.[327] 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,[328] 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."[329] 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.[330]

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.[331] Christopher Hodges[332] 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).

330. *See United Kingdom*, [1997] 3 C.M.L.R. 941, at ¶ 39 (holding European Commission had failed to make out its allegation). *See also* PEARL, *supra* note 38, at 23 (noting failure of European Commission to make out its allegation of incompatibility of Consumer Protection Act provision and Directive provision).

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).

332. *See* Report for the Commission of the European Communities on the Application of Directive 85/374/EEC on Liability for Defective Products, Study Contract No. ETD/93/B5-2000/MI/06, at 46, *available at* http://europa.eu.int/comm/internal_market/en/goods/prodliability.htm. Mr. Christopher Hodges was contracted by

fessor 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]

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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).

336. *See* Hodges, *Unanswered Questions*, *supra* note 49, at 563 (stating insurance model breaks down with unquantifiable but potentially overwhelming litigation); PRODUCT LIABILITY RULES IN OECD COUNTRIES (Organization for Economic Co-Operation and Development, Sept. 1995) (noting breakdown of insurance model with unknown risks).

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.[339] 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.[340]

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.[341] Specifically, Hodges evaluated the European Court of Justice's requirement that the state of scientific and technical knowledge be discoverable[342] with consideration of accessibility of knowledge.[343] Hodges pointed to the Court's importation of the reasonableness test in determining accessibility,[344] 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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excessive testing would discourage innovation). *See also* Council Directive No. 65/65/EEC, *amended by* Council Directive No. 87/21/EEC, O.J. L 15/36 (1987) (stating as Fourth Recital "Whereas, however, there are reasons of public policy for not conducting repetitive tests on humans or animals without over-riding cause").

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.[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.[346]

In contrast to Hodges & Professor Stapleton, Geraint Howells & Professor Mark Mildred criticized AG Tesauro as undermining the EC policy of strict product liability.[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.[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.[349] Howells & Mildred further argued that the Court's importation of an accessibility requirement is "both gratuitous and illogical."[350] According to Howells & Mildred, computerized databases allow producers to educate themselves before putting a product in production and circulation.[351] Thus, if the knowl-

345. Hodges, *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). *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).

346. *See* Stapleton, *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").

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

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

349. *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).

350. *Id.* at 572 (questioning how knowledge could be discoverable but not available).

351. *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.[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.[353] They criticized Newdick as confusing negligence and strict liability as found in the Directive.[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.[355] They reasoned that the modest levels of damages in the Member States, specifically the unavailability of punitive damages in tort claims;[356] the absence of juries in civil trials;[357] and the unlawfulness of contingency fees limiting access to legal aid,[358] all serve to curb the amount of litigation likely to occur in contrast to the situation in the United States.[359]

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of knowledge before putting a product into the production stage and again before putting it into circulation").

352. *See* Mildred & Howells, *supra* note 171, at 572 (asserting that given computerized databases, producers have access to published knowledge before putting a product into circulation).

353. *See* Howells & Mildred, *supra* note 39, at 987 (arguing that defense runs counter to rationale of strict liability).

354. *See id.* at 1011 (stating Newdick's arguments indicate confusion between negligence and strict liability regimes).

355. *See id.* at 1013 (noting no perceptible increase in insurance premiums of decrease in availability of coverage since Directive came into effect). *See also* First Report, *supra* note 52, at 2 (noting no apparent increase in level of insurance premiums); Report, *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 polices had not increased considerably).

356. *See* Howells & Mildred, *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), *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).

357. *See* Howells & Mildred, *supra* note 39, at 1013 (reporting absence of jury trials in Member States); Hodges, Panel discussion, supra note 356, at 7 (remarking that in Europe, juries do not decide questions of liability).

358. *See* Howells & Mildred, *supra* note 39, at 1013 (mentioning unlawfulness of contingency fees in Member States); Hodges, Panel discussion, *supra* note 356, at 7 (noting absence of contingency fees in Member States).

359. *See* Howells & Mildred, *supra* note 39, at 1013-14 (explaining structural difference between European and U.S. litigation systems); Hodges, Panel discussion, *supra* note 356, at 6-7 (reporting differences in legal culture between Europe and United States).

5. National Interpretation of Development Risk

To date, only a handful of cases have considered the development risk defense.[360] 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.[361] The German Supreme Court rejected the development risk defense holding that the Article 7(e) defense was not available for manufacturing defects.[362] In another German case, several customers were infected with hepatitis A from ingesting a contaminated blackberry cake.[363] The owner of the restaurant asserted that the defect in the cake was undiscoverable.[364] 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.[365]

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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.*

361. *See* THE GERMAN LAW OF TORTS: A COMPARATIVE TREATISE 584 (4th ed. 2002) [hereinafter GERMAN LAW OF TORTS] (translating Entscheidungen des Bundesgerichtshofes in Zivilsachen [BGHZ] [Supreme Court] 129, 353 (1995) (F.R.G.)). *See also* PEARL, *supra* note 38, at 37-38 (discussing exploding bottle case); Christopher Hodges, *The Case of the Exploding Bottle of Water*, 18 PRODUCT LIABILITY INT'L 73 (1996) (discussing German Federal Supreme Court's decision).

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,[366] 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.[367] In that case, the plaintiff contracted HIV when he received blood for cardiac surgery.[368] 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.[369]

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*.[370] In *Abouzaid v. Mothercare (UK) Ltd.*,[371] 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).

367. *See* Hartman/Stichting Sanquin Bloedvoorziening, 3 februari 1999, NJ 621 [Hartman v. Foundation Sanquin of Blood Supply, District Court of Amsterdam, Feb. 3 1999, NJ 621]. *See* Hodges, *Politics, Reform and Reality*, *supra* note 23, at 124 (discussing Hartman v. Stichting Sanquin Bloedvoorziening, Feb. 3 1999, NJ 1994, nr. 621 and stating that full text copy of case was unavailable in English at time of publication of article). *See also* A & Others, [2001] 3 All E.R. 289, ¶ 53(iv) (discussing Scholten case); Richard Goldberg, *Paying for Bad Blood: Strict Liability after the Hepatitis C Litigation*, 10 MED. LAW REV. 165, 198-99 (2002) (referring to Scholten v. Foundation Sanquin of Blood Supply, Feb. 3, 1999, County Court of Amsterdam). The author assumes that the Hartman case discussed by Hodges and the Scholten case discussed in *A & Others* and by Goldberg are the same case since the facts seem identical.

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).

370. *See* Abouzaid v. Mothercare (UK) Ltd., Case No. B3/2000/2273, 2000 WL 1918530 (Eng. C.A.); Richardson v. LRC Products Ltd., 2000 Lloyd's Rep. Med. 280 (Q.B. Div'l Ct. 2000); A & Others v. The National Blood Authority and Others, 3 All E.R. 289 (Q.B. Div'l Ct. 2001).

371. Case No. B3/2000/2273, 2000 WL 1918530 (Eng. C.A.).

elasticated straps.[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.[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.[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.[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.[376] The important thing was that the public was entitled to expect more from the producer.[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.[378] Not having thought of that simple test was not excusable.[379]

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372. *See* Abouzaid v. Mothercare (UK) Ltd., Case No. B3/2000/2273, 2000 WL 1918530, ¶ 2 (Eng. C.A.) (noting fleece-lined sleeping bag for respondent's younger brother); *Ignorance Not Bliss For Producers*, POST MAG., May 31, 2001, at 8 [hereinafter *Ignorance Not Bliss*] (explaining sleeping bag was secured by elasticated straps).

373. *See Abouzaid*, 2000 WL 1918530 at ¶¶ 2, 4 (remarking on accident which caused severe damage to twelve-years old child's eye); *Ignorance Not Bliss*, *supra* note 372, at 8 (reporting twelve-year-old boy lost eyesight because elasticated strap sprung back hitting him in eye).

374. *See Abouzaid*, 2000 WL 1918530 at ¶ 28 (commenting that Mothercare sought to rely on evidence that Department of Trade and Industry accident database did not have any record of comparable accident); *Product is Defective Irrespective of History of Previous Accidents*, TIMES, Feb. 20, 2001, at Features [hereinafter *Product is Defective*] (asserting defendants sought protection under development risk defense).

375. *See Abouzaid*, 2000 WL 1918530 at ¶ 29 (holding that defect was present whether or not previous accidents had occurred); *Product is Defective*, *supra* note 374, at Features (pointing out that Lord Justice Pill found defect was present even if no previous accidents occurred).

376. *See Abouzaid*, 2000 WL 1918530 at ¶ 27 (expressing Court's role is not to determine what should have been done).

377. *See id.* (arguing members of public were entitled to expect more from Mothercare); *Product is Defective*, *supra* note 374, at Features (stating that there were no relevant technical advances which would affect public expectation).

378. *See Abouzaid*, 2000 WL 1918530 at ¶ 46 (remarking that simple practical test would have been sufficient to discover defect); *Product is Defective*, *supra* note 374, at Features (reporting that Lord Justice Chadwick pointed out that potential risks of attaching metal buckle to elasticated strap ought to have been known without need for testing).

379. *See Abouzaid*, 2000 WL 1918530 at ¶ 46 (asserting that only reason simple test

A year later, Mrs. Richardson sued LRC Products when the condom her husband was using failed, causing her to become pregnant.[380] Although the case was dismissed on other grounds,[381] 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.[382]

Finally, in a case that has caused some debate over the development risk defense, Justice Burton held in *A & Others v. National Blood Authority*[383] 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.[384] *A & Others* is a class action suit brought by over a hundred claimants who had been infected with Hepatitis C through blood transfusions.[385] 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.[386] In a judgment that

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was not carried out was 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).

383. 3 All E.R. 289 (Q.B. Div'l Ct. 2001).

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*,[387] went through case law dealing with the development risk defense from other EC countries[388] and considered academic literature on the defense.[389] Burton then concluded that since the risk of infection was known, the producers continued to produce and supply the product at their own risk.[390] 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.[391] Ultimately, Burton held that since the risk of Hepatitis C infection was known, the development risk defense did not apply.[392]

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.[393] Generally speaking, manufacturers are exempt from liability for design defects that reflect unavoidable risks.[394] Under the *Restatement* (*Second*), imposition of liability for unknowable risks depends largely

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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 manufactures for unavoidably unsafe products).

on whether the consumer expectation standard[395] or the risk-utility standard is used to access defectiveness.[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.[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.[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.[399] In eliminating the consumer expectation test, the *Restatement (Third)* has recognized U.S. product liability law's return to negligence.[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.[401] It is true that consistent with the United States,[402] the German courts interpreting the Directive have decided that the development risk defense is inapplicable for manufacturing defects.[403] Furthermore, the ruling

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

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).

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

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).

399. *See supra* notes 231-32 and accompanying text (observing role of state-of-the-art evidence in predicting liability for unknown defects).

400. *See supra* note 281 and accompanying text (reporting how *Restatement (Third)* reflects U.S. product liability law's return to negligence).

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)*).

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

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]

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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*[414] and by Justice Burton's ruling in *A & Others*.[415] 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.[416] 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,[417] and the forgiveness of *comment k* for unavoidably unsafe products.[418]

The controversies surrounding the development risk defense are unlikely to subside. The differing treatment of contaminated blood in the Netherlands[419] and the United Kingdom[420] 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.[421] 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.[422] 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.[423] One important difference in the EC interpretation of the development risk defense is that producers

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.[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,[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.[426] The impact on pharmaceutical manufacturers is enormous.[427] As was feared by Hodges and Professor Stapleton,[428] the extremely narrow interpretation of the development risk defense has made it essentially worthless to producers.[429] With pharmaceutical research and development stunted by concerns of liability,[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.

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

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

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

427. *See supra* note 13 and accompanying text (noting importance of development risk defense to pharmaceutical sector).

428. *See supra* note 341 and accompanying text (arguing narrow interpretation of defense would be make it impracticable).

429. *See supra* note 286 and accompanying text (pointing out that many practitioners and academics feel that narrow interpretating of defense has made it defense of little value).

430. *See 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).