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## Bugs in Anglo-American Products Liability

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# BUGS IN ANGLO-AMERICAN PRODUCTS LIABILITY

JANE STAPLETON\*

I.	INTRODUCTION .....	1226
II.	ROUGH COMPARISON OF COMMON LAW SYSTEMS: FORM AND SUBSTANCE OF PRODUCT REGIMES .....	1228
III.	ORIENTATION OF UNITED STATES PRODUCTS REGIMES .....	1228
IV.	ORIENTATION OF THE EUROPEAN UNION DIRECTIVE AND ITS CLONES .....	1230
V.	PREMANUFACTURE GENERIC INFECTION CASES .....	1232
VI.	PREMANUFACTURE GENERIC INFECTIONS: SOME UNITED KINGDOM STATISTICS .....	1234
VII.	RESPONSE OF THE RESTATEMENT THIRD .....	1238
VIII.	RESPONSE OF THE DIRECTIVE AND ITS CLONES: THE PROBLEM OF THE EUROPEAN COMMISSION AND THE “OFFICIAL” RECORD .....	1243
IX.	RESPONSE OF THE DIRECTIVE AND ITS CLONES: THE HEPATITIS C JUDGMENT .....	1249
X.	OTHER RESPONSES TO PREMANUFACTURE GENERIC INFECTION CASES .....	1252
XI.	CONCLUSION .....	1254
	APPENDIX A .....	1256
	APPENDIX B .....	1258
	APPENDIX C .....	1259

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## I. INTRODUCTION

The face of European products liability may be about to change considerably. The first places where change probably will occur are in the procedural and funding areas. Though the density of European products cases has been and probably will continue to be slight compared to that in the United States, it is of note that a growing trend within the European case law is a shift to multi-party actions. Proposed procedural rule changes are about to fuel this shift.<sup>1</sup> At the same time, fundamental changes in the way civil litigation is funded within European Union Member States have disproportionately encouraged group actions.<sup>2</sup> They have also shifted greater risk, responsibility, and power to plaintiffs' lawyers.

On the legislative front, the reform of the separate European products liability doctrine, set out in the 1985 *European Directive on Product Liability*,<sup>3</sup> is on hold. Following both a Green Paper<sup>4</sup> and a White Paper,<sup>5</sup> the European Commission (the "Commission") concluded that it had insufficient evidence to advise on the future of the Directive at present, and thus, it has both set up an expert advisory committee and funded two major research studies on products liability in Europe. These studies are to collect information, particularly on the costs that might result from any future repeal of the most controversial defence in the Directive. Very significantly, one of the commissioned studies has been set to the task of investigating the feasibility of introducing a uniform products liability system across the European Union (EU), replacing the divergent national rules (for

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1. For an excellent study of this phenomenon see CHRISTOPHER HODGES, MULTI-PARTY ACTIONS (2001); see also LORD CHANCELLOR'S DEP'T, CONSULTATION PAPER, REPRESENTATIVE CLAIMS (Feb. 2001), at <http://www.lcd.gov.uk/consult/general/repclaims.htm> (last visited May 6, 2002); Christopher Hodges, *Multi-Party Actions: A European Approach*, 11 DUKE J. OF COMP. & INT'L L. 321 (2001); Christopher Hodges, *Factors Influencing the Incidence of Multiple Claims*, 4 J. PERS. INJURY LITIG. 289 (1999).

2. For example, the European Commission has published a proposal for a Directive establishing minimum common rules relating to legal aid and other financial aspects of civil proceedings in cross-border disputes at COM(2002)13 final. See *The Problems Confronting the Cross-Border Litigant*: Green Paper from the Commission on Legal Aid in Civil Matters, COM(2000)51 final; *Access of Consumers to Justice and the Settlement of Consumer Disputes in the Single Market*: Green Paper from the Commission, COM(93)576 final. On the recent introduction in the United Kingdom of conditional fees, which are not contingency fees, but "no-win no-fee" arrangements, see LORD CHANCELLOR'S DEP'T, REGULATORY IMPACT ASSESSMENT: IMPROVEMENT IN THE AVAILABILITY AND USE OF CONDITIONAL FEES (Nov. 1998).

3. See Council Directive 85/374, 1985 O.J. (L 210) 29 [hereinafter Directive] (addressing approximation of the laws, regulations, and administrative provisions of the Member States concerning liability for defective products).

4. Liability for Defective Products: Green Paper from the European Commission, COM(99)396 final; see Jose J. Izquierdo Peris, *Liability for Defective Products in the European Union: Developments Since 1995—The European Commission's Green Paper*, 1999 CONSUMER L.J. 331.

5. Commission Report on the Application of Directive 85/374 on Liability for Defective Products, COM(2000)893 final; see Donna Lambert, *European Strict Product Liability Laws*, EUROPEAN PROD. LIAB. REV. March 2001, at 16. This was the second report; the first was Commission Report on the Application of Directive 85/374, COM(95)617 final.

example, in contract and under sales legislation) that co-exist with the Directive.<sup>6</sup> The parallel with the aim of the Reporters of the *Restatement (Third) of Torts: Products Liability (Restatement Third)* should not go unnoticed.<sup>7</sup>

Why should any of this be of interest to U.S. lawyers? First, every jurisdiction has a haphazard experience. By considering the contrasting experience and response of other legal systems, U.S. lawyers may be alerted to challenges their own system may have to confront. Secondly, the comparison of how other legal systems have reacted to a particular socio-economic phenomenon can highlight neglected gaps and baseless assumptions in the U.S. system. My aim here is to sketch, for U.S. eyes, the contrasting state of products liability doctrine in Europe and those foreign jurisdictions that have adopted clones of the European Directive. But the focus I will use, the lens on our different experiences, will be how regimes are responding to the increasing challenge of pathogenically infected products—as the title of this Essay puts it, “bugs” in products liability. These range from well-known bacterial infections, such as Salmonella, Legionella, and Escherichia-coli 0157 (E coli),<sup>8</sup> to viral infections, such as the infection of blood by the Human Immuno-Virus (HIV)<sup>9</sup> and Hepatitis C (Hep C),<sup>10</sup> to diseases, such as Bovine Spongiform Encephalopathy (BSE) and Creutzfeldt-Jakob Disease (CJD).<sup>11</sup>

6. John Meltzer et al., *European Commission Launches Major Product Liability Study*, EUROPEAN PROD. LIAB. REV., Dec. 2001, at 4.

7. RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY (1998) [hereinafter RESTATEMENT THIRD]. In the *Restatement Third* § 2 comment *n*, the Reporters sought, at the level of something they called “functional requisites,” to amalgamate causes of action which rely on identical facts. See also James A. Henderson, Jr. & Aaron D. Twerski, *Achieving Consensus on Defective Product Design*, 83 CORNELL L. REV. 867, 918 (1998) [hereinafter *Achieving Consensus*] (“So long as the functional requisites of section 2 are satisfied, plaintiffs may couch their design claims in negligence, implied warranty, or strict liability in tort.”). Whether this will succeed in producing a general simplification of products liability litigation is a matter of some controversy. The problem here lies not so much with the amalgamation of claims that might previously have been argued both under RESTATEMENT (SECOND) OF TORTS § 402A (1965) (RESTATEMENT SECOND) and negligence theory, for the duplicative nature of many such claims is fairly well agreed. The difficulty lies in knowing where warranty claims fit in and whether the full extent of existing warranty entitlements is reflected in the *Restatement Third*. See Jane Stapleton, *Restatement (Third) of Torts: Products Liability, An Anglo-Australian Perspective*, 39 WASHBURN L.J. 363 (2000).

8. See also the following: campylobacter bacteria, cryptosporidium, listeria, botulism, psittacosis, and mycobacterium avium subspecies paratuberculosis.

9. See, e.g., Simon Garfield, *THE END OF INNOCENCE: BRITAIN IN THE TIME OF AIDS* (1994).

10. See also the following: the Ebola virus (It is now thought that the Black Death was caused by this virus being passed from person to person, not via infected rats. Robert Uhlig, *Black Death Caused By ‘Ebola’ Virus, Not Rats*, DAILY TEL. (London), Nov. 22, 2001); Q fever, rhizopus, the foot and mouth virus, and the smallpox virus.

11. See JENNIFER COOKE, *CANNIBALS, COWS & THE CJD CATASTROPHE* (1998); DOUGLAS POWELL & WILLIAM LEISS, *MAD COWS AND MOTHER’S MILK* (1997); SHELDON RAMPTON & JOHN STAUBER, *MAD COW U.S.A.* (1997); RICHARD RHODES, *DEEPLY FEASTS: TRACKING THE SECRETS OF A TERRIFYING NEW PLAGUE* (1997) (detailing the controversy as to the form of the infective agent in transmissible spongiform encephalopathies); Clive Martyr, *BSE in Europe*, EUROPEAN PROD. LIAB. REV., March 2001, at 4; Organic Consumer’s Ass’n, *Mad Cow Disease* available at <http://www.OrganicConsumers.org/madcow.htm> (last visited May 6, 2002).

## II. ROUGH COMPARISON OF COMMON LAW SYSTEMS: FORM AND SUBSTANCE OF PRODUCT REGIMES

The divergence of the U.S. system from other common law systems is considerably more striking than that between those other common law systems and the civil law systems in the EU. This fact is easily set out in a rough comparison of substantive and legal system characteristics such as that in Appendix A.

In relation to the special products liability rule, the manifestation of this U.S. divergence that is most obvious to students is length. In the United States, the seminal doctrinal treatment is the *Restatement Third*, published in 1998 which runs 382 pages. Contrast this with the Directive, which occupies a little over four pages in the *Official Journal of the European Communities*, or compare reported case law.<sup>12</sup> One of the first cases to deal with the *Restatement Third* ran to only eight pages;<sup>13</sup> one of the first cases to apply the Directive in the United Kingdom ran to 113 pages.<sup>14</sup>

But there is no mystery here. A non-U.S. jurisdiction, with a uniformly high-quality judiciary, single court of final appeal, tight system of precedent, and active legislature, can often “make do” with a very sparse formulation of its binding legislative rules. Such foreign jurisdictions accomplish this task because the legal rules are definitively elaborated in a unitary appellate case law and because academic treatises serve broadly the same role as the Comments and Reporters’ Notes of the *Restatement Third*. Similarly, in jury-free systems, the triers of fact must provide written reasons for their determinations, and this often produces very lengthy expositions of legal reasoning.

## III. ORIENTATION OF UNITED STATES PRODUCTS REGIMES

Section 402A of the *Restatement (Second) of Torts (Restatement Second)*<sup>15</sup> was a top-down law reform motivated, not by social or forensic pressures, but by the enthusiasm of a small group of Legal Realists that saw the opportunity to make what they saw as a small win-win change to legal entitlements. Out of, what I call “classical” (because privity bounded) warranties,<sup>16</sup> a new cause of action had grown; under the tag of strict liability “warranty” claims, plaintiffs were in fact being allowed to sue manufacturers with whom they had no contractual privity—what I call “aclassical” warranty claims. If this were so, and if elsewhere, disguised as “negligence” liability, courts were in fact covertly imposing strict liability for manufacturing errors in products, then it seemed to make sense to

12. See *supra* note 3.

13. *Delaney v. Deere & Co.*, 985 F. Supp. 1009, 1017 (D. Kan. 1997) (concerning the grant of defendant’s motion for summary judgment). For the appeal, see *Delaney v. Deere & Co.*, 999 P.2d 930 (Kan. 2000).

14. *In re Hepatitis C Litig. (A v. Nat’l Blood Auth.)*, 3 All E.R. 289 (Q.B. 2001).

15. *RESTATEMENT SECOND*, *supra* note 7, § 402A.

16. JANE STAPLETON, *PRODUCT LIABILITY* 16-20 (1994) (describing classical warranties as those involving traditional contractual privity between the parties).

clarify this state of affairs by recognizing a separate class of strict liability in tort for products defects. The apparent neatness, low impact, and intellectual glamour of this move led its promoters to overlook major gaps in the theoretical foundations of the rule in the new § 402A. Traditional incidents of the warranty claim, such as its limit to products and further, to only those products that had been commercially supplied were limits that were explicable in classical privity-based warranty claims. But these limits were then carried over holus-bolus into the *Restatement Second* with little or no attempt at justification. Little, if any, concern seems to have been raised about the fresh anomalies that would be created by separate tort liability for commercially supplied products. Indeed, it was a revealing feature of the work of products liability theorists that most resorted to ignoring the destabilizing phenomenon of bystander injuries before stating a theory of the law,<sup>17</sup> while the work of general tort theorists, such as Jules Coleman, abandoned any attempt to accommodate products liability within their scheme of “core” tort law concepts.<sup>18</sup>

Given current product regimes and controversies, it is noteworthy that, in general, the *Restatement Second* contained no separate black-letter treatment of specific product types such as blood, had no separate treatment of types of product defect, and gave no guidance on what might constitute a product defect.<sup>19</sup> These oversights may be explained by the fact that, although the *Restatement Second* was not explicitly limited to manufacturing errors, it was clearly intended as a reform focused on products defects introduced by the manufacturing process. In such cases, the production line norm offered what seemed to be a simple benchmark for the requirement of a “defect.” This unexpressed focus on manufacturing errors had a critical effect on the development of U.S. tort law. Together with the lack of a domestic thalidomide tragedy in the United States, this focus led the drafters of the *Restatement Second* to overlook the legal dilemma posed by unforeseeable side effects of a product’s intended design.

The 1998 *Restatement Third* is a considerable contrast to the *Restatement Second*. In constructing the *Restatement Third*, its Reporters were centrally concerned with perceived bottom-up pressure on the U.S. products regime from “classic design cases.”<sup>20</sup> The most common expression of these claims is where the plaintiff argues that the product did not perform its intended function sufficiently

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17. See *id.* at 127 & n.13.

18. See, e.g., JULES L. COLEMAN, *RISKS AND WRONGS* (1992) (defending and criticizing economic analysis of tort concepts). In particular, see Chapter 20 for Coleman’s analysis of product liability theory. *Id.* at 407-29.

19. But see RESTATEMENT SECOND, *supra* note 7, § 402A cmt. k; see also George W. Conk, *Is There a Design Defect in the Restatement (Third) of Torts: Products Liability?*, 109 YALE L.J. 1087, 1091-1101 (2000) (discussing the history of § 402A and its application, through comment k, to “unavoidably unsafe” products such as drugs, cigarettes, and alcoholic beverages).

20. So-called “classic design cases” are ones that “do not involve product malfunctions, violations of safety regulations, or egregiously dangerous products.” 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, 17 (1999) [hereinafter *New American Restatement*]. Yet, “the plaintiffs nevertheless plausibly claim that the designs are unacceptably dangerous, and therefore, legally defective.” *Achieving Consensus*, *supra* note 7, at 876-77 (1998)

well: a chair or axle was “not strong enough,” the side-panels of a car were “not strong enough” in a crash, and so on. While the *Restatement Third* gives separate treatment to classes of product claims according to certain proof shortcuts<sup>21</sup> and according to certain product classes such as food,<sup>22</sup> the main focus of the Reporters is on the residual class in § 2 under which they accept that most classic design cases will fall.<sup>23</sup> Section 2 gives separate treatment to three classes of product defects: manufacturing defects, design defects, and warning defects.<sup>24</sup>

Like the *Restatement Second*, the *Restatement Third* pays little attention to the defect issues on which Europeans focus so keenly—those posed by unforeseeable side effects of intended design. As a result, there is no black-letter treatment in the *Restatement Third* of how and why such cases should be treated.<sup>25</sup> However, the *Restatement Third* does try to give some guidance on the issue of defectiveness. For example, under § 2(a), manufacturing errors are not only defined as ones that depart from their intended design but are, merely by satisfying that definition, classified as defective conditions.<sup>26</sup> In contrast, design and warning conditions that fall within this residual § 2, such as most classic design cases, are to be judged by reasonableness criteria.<sup>27</sup> By implication then, this means that a product with an unforeseeable design condition that causes harm cannot, by definition, be defective. Finally, the *Restatement Third* pays no attention to the phenomenon of the waves of BSE, CJD, Hep C, and HIV infections that had been appearing since the 1980s and 90s. This oversight, as we will see, leaves such infection cases to be treated in a highly fractured manner by the *Restatement Third*.

#### IV. ORIENTATION OF THE EUROPEAN UNION DIRECTIVE AND ITS CLONES

The orientation of the *Restatement Third* is in marked contrast to that of the EU Directive and its clones in other countries such as Japan, Australia, Taiwan, and Israel.<sup>28</sup> The Directive did not result from some perceived bottom-up forensic pressure from claims. Rather, the engine of this reform was social and political.<sup>29</sup>

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21. See RESTATEMENT THIRD, *supra* note 7, § 3 (“Circumstantial Evidence Supporting Inference of Product Defect,” describing a sort of generously reinterpreted *res ipsa loquitur* class); see also *id.* § 4 (“Non-compliance and Compliance With Product Safety Statutes or Regulations”); *id.* § 2 cmt. e (dealing with “manifestly unreasonable design,” other terms for which are categorically defective design, generically defective design, and egregiously dangerous product type).

22. See *id.* § 7; see also *id.* § 5 (components); *id.* § 6 (prescription drugs and medical devices); *id.* § 8 (used products).

23. See generally Stapleton, *supra* note 7 (discussing the odd positioning of the “residual” section at the beginning of the Restatement and criticizing other features of the *Restatement Third*).

24. RESTATEMENT THIRD, *supra* note 7, § 2.

25. There are two passing mentions in the non-black-letter text. See RESTATEMENT THIRD, *supra* note 7, § 2 cmt. 1; § 6 cmt. g (relating to prescription drugs and medical devices).

26. *Id.* § 2(a).

27. *Id.* § 2(b), (c).

28. See PRODUCT LIABILITY IN THE ASIA-PACIFIC (Jocelyn Kellam ed., 2d ed. 1999); Luke Nottage, *The Present and Future of Product Liability Dispute Resolution in Japan*, 27 WM. MITCHELL L. REV. 215 (2000).

29. STAPLETON, *supra* note 16, at 37-65.

In particular, the concern of the public in these countries had been galvanized by the disaster caused by the unforeseen side effects of the Thalidomide pregnancy drug.<sup>30</sup> Meanwhile, by the late 1970s, the European Commission was keen to promote consumer protection measures to show Europeans that the “common market” was not there simply to serve big business. It proposed very pro-consumer draft Directives in 1976 and 1979.<sup>31</sup> Yet there remained intense concern within the European Parliament and the Council that substantial exculpatory provisions be included in any future Directive.<sup>32</sup>

As a result, the Directive is one of the high-water marks of Euro-fudge and textual vagueness.<sup>33</sup> It used a cryptic “definition” of defect in Article 6<sup>34</sup>: “A product is defective when it does not provide the safety which a person is entitled to expect, taking all circumstances into account . . . .”<sup>35</sup> It also allows a Member State discretion on a number of critical matters including the exculpatory Article 7(e), which became known as the “development risk defence;” Article 7(e) would allow a manufacturer to escape liability if it can prove that “the state of scientific and technical knowledge at the time when it put the product into circulation was not such as to enable the existence of the defect to be discovered.”<sup>36</sup> Article 15 allows

30. *Id.* at 39-43.

31. See Commission Proposal for a Council Directive Relating to the Approximation of the Laws, Regulations, and Administrative Provisions of the Member States Concerning Liability for Defective Products, 1976 O.J. (C241) 9 [hereinafter First Draft Directive]; Commission Amendment of the Proposal for a Council Directive Relating to the Approximation of the Laws, Regulations, and Administrative Provisions of the Member States Concerning Liability for Defective Products, 1979 O.J. (C271) 3 [hereinafter Second Draft Directive].

32. See, e.g., Economic and Social Committee (ECOSOC) Report on Proposal for a Council Directive on Liability for Defective Products, COM(76)372 final at 41-45 [hereinafter ECOSOC Report] (stating that industry should not be made “liable for products which could not have been made to a safer standard at the time when they were put into circulation;” “it may be in the patients’ interests to put into circulation products which are known to have side-effects when taken by some or indeed all persons. . . .;” also note early concern about the uncertainty of the concept of undiscoverability in the comment “scientists might be far less willing than lawyers to define what at the present level of technological and scientific development is (‘undiscoverable’) as opposed to undiscovered. Undiscoverability is itself very doubtful from a scientific point of view;” note the view of the Section for Industry, Commerce, Crafts, and Services against inclusion of liability for development risks emphasizing that their inclusion “could have an inhibiting effect on innovation.” *Id.* at 44-45.

See also the following reports of the Legal Affairs Committee of the European Parliament raising the concern that liability for development risks might inhibit innovation: EUR. PARL. DOC. (COM 246) 26-27 (1978); EUR. PARL. DOC. (COM 71) 16-17 (1979).

33. See *infra* note 117 and accompanying text.

34. It was at the initiation of the Legal Affairs Committee of the European Parliament that the definition of defect included this statement that the Court should be required to “take into account all the circumstances” of the particular case. EUR. PARL. DOC. (COM 71) 18 (1979). Specifically, there should be a reference to time to make “it clear that the user of an old product cannot expect the same degree of safety from such a product as from a product which has just been put into circulation.” *Id.* Characteristically, the pro-plaintiff Commission refused to include this amendment in its second draft Directive. Second Draft Directive, *supra* note 31, at 3.

35. Directive, *supra* note 3, art. 6. Such circumstances include foreseeable use and therefore, must extend to misuse.

36. *Id.* art. 7(e).



a Member State to implement the Directive in domestic legislation without that defence.<sup>37</sup> The final legislative body, the Council of Ministers, even allowed individual Member State delegations to append Unilateral Declarations to the Directive to expound their local interpretations of its provisions. The point is that the Directive tries to square a circle: it uses the rhetoric of "strict liability," and yet, in Articles 6(2) and 7(e), it seems to provide solid protection for reasonable businesses, a compromise demanded by the U.K. Government of Margaret Thatcher.<sup>38</sup>

Textually, the Directive is in certain respects quite like the *Restatement Second*. It gives no separate treatment to product types or defect types, and the definition of defectiveness in Article 6 is, at best, circular. On the other hand, just as the focus of the *Restatement Second* had been manufacturing errors and the focus of the *Restatement Third* is on classic design cases, the Directive also reflects its historical trigger: the Thalidomide disaster. Unlike the Restatements, the Directive attempts to grapple explicitly with unforeseen side effects of a product's intended design by giving product suppliers the crucial exculpatory defense in Article 7(e). However, the Directive has its own gaps; failure to reflect on the U.S. experience leaves the Directive with no provision as to how to treat classic design cases—the "how strong should a chair be" cases. Needless to say, just as the Restatements give no guide as to how infection cases should be handled, nor does the Directive address these issues.

#### V. PREMANUFACTURE GENERIC INFECTION CASES

The Reporters of the *Restatement Third* have attacked the Directive.<sup>39</sup> One of their principal complaints seems to be that it does not distinguish between types of defect.<sup>40</sup> This omission then blocks the Directive from adopting what the Reporters say is "the [o]nly [s]ensible [s]tandard for [d]efect in [c]lassic [d]esign [c]ases."<sup>41</sup> This is, they argue, the requirement of convincing proof of a reasonable alternative design, a requirement the *Restatement Third* does not impose on plaintiffs in manufacturing error cases.<sup>42</sup> But what if the case in favor of separating out types of defect is itself dubious? This has always been one of the core dilemmas in modern products liability and yet again, it is being neatly exposed, this time by premanufacture generic infection cases.

Premanufacture generic infection cases are a discrete type of case, distinct from cases of chemical contamination, such as when a worker carelessly puts the wrong chemical into the water storage pond of a water supply company,<sup>43</sup> or a delivery

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37. *Id.* art. 15.

38. *Id.* arts. 6(2), 7(c).

39. *New American Restatement*, *supra* note 20.

40. *Id.* at 13-14.

41. *Id.* at 19 (emphasis added).

42. *Id.*

43. *A.B. v. S.W. Water Servs. Ltd.*, 1993 Q.B. 507 (Eng. C.A. 1992).

person incorrectly mixes fire retardant chemical with stock feed.<sup>44</sup> Unlike chemical contamination cases, in premanufacture generic infection case, the danger lies in the presence of a transmissible pathogen. By definition, *premanufacture* generic infection cases are distinct from cases where a product is contaminated or infected during the production process. They are cases where the infection in a product was present in the raw materials and, therefore, before manufacture of the product.<sup>45</sup> Pathogenic infections can be isolated events; take, for example, a local outbreak of “wool-sorter’s disease” caused by one anthrax-infected sheep,<sup>46</sup> Legionnaires’ disease contracted from one infected piece of machinery,<sup>47</sup> or the sort of E-coli 0157 infection from one contaminated batch of food that killed twenty-one people in Lanarkshire in 1996.<sup>48</sup> But the sharpest lessons from infection cases come from those where it is feared that the infection is *generic* to a product class as in the case of BSE, foot and mouth disease, and other recent epidemics.<sup>49</sup>

To sum up the characteristics I have used to define pre-manufacture generic infection cases:

- (1) The infection is not part of the condition of the product which the supplier “intended” in the sense of “desired;”
- (2) The infection was present before any artificial “manufacturing” process occurred;
- (3) The infection is, however, known or suspected to be “generic” in the sense that it has affected an entire product sector such as the beef industry, the blood product sector, or the water supply;

44. In 1973, toxic chemicals were accidentally fed to dairy cattle in the State of Michigan with the result that virtually all nine million in the state’s human population became permanently contaminated by the hazardous chemical polybrominated biphenyl. See JOYCE EGGINTON, BITTER HARVEST 14, 275, 281 (1980). Scientists estimated “that only about 10% of the body burden of PBB contamination being carried by nine million people would be excreted in their lifetimes.” *Id.* at 307; see also Mich. Chem. Corp. v. Am. Home Assurance Co., 728 F.2d 373, 376 (6th Cir. 1984) (involving negligent shipment of toxic-flame retardant as livestock feed additive); Oscoda Chapter of PBB Action Comm., Inc. v. Dep’t of Natural Res., 268 N.W.2d 240 (Mich. 1978) (involving suit to prevent burial of contaminated cattle in clay-lined pit).

45. See Jane Stapleton, *BSE, CJD, Mass Infections and the 3rd US Restatement*, in INTERNATIONAL PERSPECTIVES ON CONSUMERS’ ACCESS TO JUSTICE (C. Rickett & T. Telfer eds.) (Cambridge Univ. Press forthcoming).

46. The scientific name is *Bacillus anthracis*. See also the *meningococcus* infection.

47. See, e.g., Brennen v. Mogul Corp., 557 A.2d 870 (Vt. 1988) (addressing a case where a plumber sued manufacturer of water treatment equipment when he allegedly contracted Legionnaire’s Disease while working on cooling tower because manufacturer’s equipment and chemicals did not prevent growth of legionella bacteria).

48. Jonathan Leake, *New Health Alert as Coli Hits Half of Cattle Herds*, SUNDAY TIMES (London), Sept. 9, 2001, at 5G (reporting that as a result of raw meat coming in contact with cooked meat, 500 other people became ill).

49. See also Valerie Elliott, *Dairies Told To Improve Hygiene To Beat Milk Bug*, TIMES (London), Dec. 7, 2001, at 20 (writing that some scientists fear that a significant but unknown proportion of the U.K. milk supply is infected with *Mycobacterium avium* subspecies *paratuberculosis*, from which each year 90,000 people in Britain contract Crohn’s disease).

- (4) This sector is an "essential" product sector, such as milk or blood, in the sense that it does not have realistic substitutes;
- (5) The infection in the product type is not present in each item of the product but testing each item for that infection is impossible/impractical etc; and
- (6) The infection is not necessarily limited to one generation of products or victims but may be transmissible to following generations.<sup>50</sup>

#### VI. PREMANUFACTURE GENERIC INFECTIONS: SOME UNITED KINGDOM STATISTICS

Before we compare the responses of the different products liability regimes to these cases, let me sketch some of the socio-economic contexts in which Western European lawyers will be setting these claims. By far, the most high-profile recent disaster concerning premanufacture generic infection cases is the U.K. mad cow (BSE) epidemic. Some statistics may help sketch the magnitude of the problem.

By March 2002, BSE cases in the U.K. cattle population numbered 191,000,<sup>51</sup> and 5.5 million cattle had been slaughtered in an attempt to contain the plague.<sup>52</sup> However, scientists fear that BSE may have become endemic in British cattle because young cattle are being raised in fields that have been contaminated by the dung of BSE-infected cattle.<sup>53</sup> The infection has spread abroad: it is currently believed that BSE spread from the United Kingdom across Europe and further afield by infected proteins used in animal feed.<sup>54</sup> In late 2001, two cows in Japan were found to have BSE; a limited cull of cattle is now underway in that country.<sup>55</sup>

The magnitude of the public health problem in the United Kingdom is reflected in the fact that between 1980 and 1996, the number of BSE-infected animals eaten by the U.K. population is estimated to have been one million.<sup>56</sup> By January 2002, 113 people in the United Kingdom had died from Creutzfeldt-Jakob disease (CJD), the human form of BSE.<sup>57</sup> Currently, the worst-case estimate of people who are or

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50. See, e.g., Robert Uhlig, *BSE Cannot Be Inherited by Calves, Study Finds*, DAILY TEL. (London), Feb. 26, 2002. It is currently thought that BSE is transmitted between cattle by giving them food contaminated with the remains of infected animals (but not from infected mother to offspring). *But see, infra* note 66.

51. DEP'T FOR ENVIRONMENT, FOOD & RURAL AFFAIRS (DEFRA), BSE STATISTICS, at <http://www.defra.gov.uk/animalh/bse/index.html> (Last updated Mar. 1, 2002).

52. *Id.* DEFRA at <http://www.defra.gov.uk/animalh/bse/bse-statistics/level-3-scheme.html> (last visited May 6, 2002).

53. James Meikle, *Infected Fields Could Spread BSE, Scientists Say*, GUARDIAN (London), Sept. 13, 2001.

54. *USA's Mad Cow Risk is Low, Study Finds*, USA TODAY, Dec. 3, 2001, at 6D.

55. James Brooke, *Potentially Mad Cows to Die*, N.Y. TIMES, Nov. 27, 2001, at A6.

56. Roger Highfield, *Epidemic of Human BSE 'May Be at Its Peak'*, DAILY TEL. (London) Oct. 26, 2001.

57. Lorraine Fraser, *Charles Backs Controversial CJD Research*, DAILY TEL. (London), Jan. 13, 2002.

will be infected by CJD stemming from the current outbreak of BSE in cattle is 136,000, of whom 40,000 will die of the disease despite its long incubation period because they were sufficiently young when infected.<sup>58</sup> Faced with civil claims from families affected by CJD,<sup>59</sup> the U.K. Department of Health set up a £55 million compensation trust fund.<sup>60</sup> This amount is likely to be grossly inadequate if BSE has infected the national sheep herd. If such is the case, the U.K. government has announced that the entire flock of 40 million sheep will be culled.<sup>61</sup> Even with such a cull, the worst-case estimate of future vCJD deaths if sheep have been infected with BSE, is around 150,000.<sup>62</sup> Also, it is already known that CJD has been contracted through infected products from human bodies, such as dura mater, transplant tissue, human growth hormone, and fertility products.<sup>63</sup> It is feared that human CJD infection may occur through the possible *generic* infection of a number of product sectors (that is, where it is suspected that there is a risk of infection but no way of screening and isolating all particular cases of infection) such as vaccines (and other blood products such as plasma),<sup>64</sup> meat,<sup>65</sup> gelatin,<sup>66</sup> dairy products,<sup>67</sup>

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58. Mark Henderson, *Number of vCJD cases 'Will Not Exceed 40,000,'* TIMES (London), Oct. 26, 2001.

59. The civil cases, known as the *Creutzfeldt-Jakob Disease Litig.*, may be found at the following: 54 B.M.L.R. 1 (Q.B. 1995) (No. 1); 54 B.M.L.R. 8 (Q.B. 1996) (Nos. 2, 4); 54 B.M.L.R. 79 (Q.B. 1996) (No. 3); 54 B.M.L.R. 85 (Q.B. CA 1997) (Nos. 2, 4); 54 B.M.L.R. 92 (Q.B. 1997) (No. 5); 54 B.M.L.R. 95 (Q.B. 1998) (No. 6); 54 B.M.L.R. 100 (Q.B. 1998) (No. 7); 54 B.M.L.R. 104 (Q.B. 1998) (No. 8); 54 B.M.L.R. 111 (Q.B. 1998) (No. 9).

60. *£155,000 for vCJD Victim An Insult*, TIMES (London), Nov. 17, 2001, at Scotland 6.

61. *Plan to Cull All Sheep if BSE is Found*, DAILY TEL. (London), Sept. 28, 2001.

62. Mark Henderson, *Sheep Meat May Pose Massive CJD Risk*, TIMES (London), Jan. 10, 2002, at 8; Roger Highfield, *Scientists Refuse to Rule Out Epidemic of vCJD from Sheep*, DAILY TEL. (London), Jan. 10, 2002.

63. See COOKE, *supra* note 11; RAMPTON & STAUBER, *supra* note 11, at 71; RHODES, *supra* note 11, at 131-51.

64. The U.K. government concedes that blood products including vaccines may be at risk of contamination by CJD. Lois Rogers & Bryan Christie, *Scientists Warn of CJD Risk in Child Vaccines*, SUNDAY TIMES (London), Feb. 22, 1998, at 7. Thenceforward, the Department of Health advised (a) that the CJD risk with current blood supplies was "theoretical," but (b) that experts agree that there is no way of guaranteeing this. See HOUSE OF LORDS DEBATES, 590 Hansard 680 (June 5, 1998) available at <http://www.publications.parliament.uk/pa/ld/ldhansard.htm> (last visited May 6, 2002); HOUSE OF LORDS DEBATES, 611 Hansard 985 (Mar. 30, 2000); HOUSE OF COMMONS DEBATES, 345 Hansard 124 NH (Mar. 7, 2000), available at <http://www.publications.parliament.uk/pa/cm/cmhansard.htm> (last visited May 6, 2002).

65. Continuing uncertainty on this issue is reflected in the fact that the U.K. government is funding the research of minority-view scientists who suspect beef is not the cause of CJD. Valerie Elliott, *Scientists to Test if Beef is the Cause of CJD*, TIMES (London), May 18, 1999, at 15; METRO (London) Oct. 12, 2001. Some postulate a key role for divalent cations such as Manganese, which is found in many manufacturing processes and in pesticides. George Monbiot, *Mad Cows, Bretons and Manganese: The French Cases of BSE May Not Have Been Spread from Britian*, GUARDIAN (London), Nov. 23, 2000.

66. RHODES, *supra* note 11, at 257.

67. David Brown, *Food Agency Urges Mass Screenings of Sheep for BSE*, DAILY TEL. (London), Nov. 1, 2000.

human blood,<sup>68</sup> human tissue,<sup>69</sup> leather or woolen clothing,<sup>70</sup> and the water supply.<sup>71</sup> In July 1996, Carleton Gajdusek, who won the 1976 Nobel Prize in Medicine for his work on transmissible spongiform encephalopathies in humans, noted that in the United Kingdom:

[A]ny species could be carrying it—dairy cows, beef cattle, pigs, chickens. . . . All the pigs in England fed on this meat-and-bone meal. . . . Probably all the pigs in England are infected. And that means not only pork. It means your pigskin wallet. It means catgut surgical suture, because that's made of pig tissue. All the chickens fed on meat-and-bone meal; they're probably infected. You put that stuff in a chicken and it goes right through. A vegetarian could get it from chicken-shit that they put on the vegetables. It could be in the tallow, in butter. . . . These people who've come down with CJD have given blood. It's undoubtedly in the blood supply. . . . And by the way, it could be in the milk.  
 . . .<sup>72</sup>

The BSE/CJD crisis and its poor handling by Member State governments and central EU authorities has had a dramatic impact on the issue of food safety in the EU, which is now recognized as a core issue in European Community policy.<sup>73</sup> In

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68. Early suspicions among a minority of scientists that CJD could be spread by blood donations is reported by Nicholas Schoon, *CJD Could Be Spread by Blood Transfusions*, INDEP. (London), Oct. 8, 1997, at 1. Plans were made to ban plasma made from pooled donations of U.K. blood donors because of CJD risk. Nigel Hawkes, *British Blood Products Banned as Too Risky*, SUNDAY TIMES (London), Feb. 27, 1998, at 1. This ban was put in place in May 1998. Joanna Blythman, *Blood on the Boil*, GUARDIAN (London), May 14, 1998. It was reported that "Britain's blood supplies are almost certainly infected with the human form of mad cow disease, the Government has been told." U.K. MAIL (London), July 6, 1998, at 20. The NHS has been reported as considering banning all transfusion recipients from donating blood, which would eliminate ten percent of donations. James Meikle, *CJD Fears Could Lead to Blood Donor Ban*, GUARDIAN (London), Nov. 21, 2000. It is feared that half the U.K. blood donors will refuse to donate from fear that the CJD screening process will reveal they are infected. James Meikle, *Blood Supplies 'Could Be Halved' as Donors Fear Results of vCJD Tests*, GUARDIAN (London), Oct. 2, 2001.

69. For an early report of suspicions of the possibility of CJD infection from donated implanted tissue, see Jeremy Laurance, *Transplant Patients Risk CJD After Receiving Tissue from Infected Woman*, INDEP. (London), Dec. 1, 1997, at 3.

70. In a 1998 study, researchers found a startling and confusing link between CJD and "exposure to leather, including wearing it." Celia Hall, *Research Fails to Find Link Between Beef and CJD*, DAILY TEL. (London), Apr. 10, 1998, at 13.

71. On suspicions that part of the U.K. water supply is contaminated with BSE/CJD, see Charles Arthur, *Animals Raise New Fear on Spread of CJD*, INDEP. (London), Aug. 30, 1997, at 8; Anthony Mitchell et al., *Don't Drink the Water*, DAILY EXPRESS (London), May 25, 2001. Similar fears exist in Ireland where a high proportion of water is contaminated with animal slurry. Lorna Siggins, *Report Attempts to Put Public's Fears in Context*, IRISH TIMES, Dec. 12, 2000, at 7.

72. RHODES, *supra* note 11, at 220-21.

73. Martyr, *supra* note 11. See also the withering report by the European Parliament on the BSE fiasco at the EU level, Resolution on the Results of the Temporary Committee of Inquiry into BSE, 1997 O.J. (C 85) 61. At the U.K. level see the Phillips inquiry at Report to an Order of the Honourable

response to this crisis, the EU amended the Directive in 1999 to remove the possibility that a Member State could bar claims concerning unprocessed primary products.<sup>74</sup>

The scientific uncertainty concerning the nature and transmission routes of these infectious diseases makes it of considerable concern that some captive and free-range deer and elk in Colorado, Montana, Nebraska, Oklahoma, South Dakota, and Wyoming suffer from Chronic Wasting Disease (CWD), a member of the transmissible spongiform encephalopathies (TSE) group of diseases which also includes BSE and CJD.<sup>75</sup> Indeed, an estimated fifteen percent of wild deer in the United States are already infected, making CWD a "front-burner" public-health concern.<sup>76</sup> Culls of thousands of U.S. deer and elk are under way.<sup>77</sup> It is significant that three hunters in America have already died of CJD.<sup>78</sup> Finally, transmissible mink encephalopathy has broken out in at least eleven U.S. milk farms.<sup>79</sup>

The *general* state of infection in human food in the United Kingdom has become a matter of grave national importance. There are between 4.5 and 5.5 million cases of food poisoning per year.<sup>80</sup> Poisonous bacteria has been found in half of all chickens sold,<sup>81</sup> while it has been reported that E-coli has been discovered in half of Britain's cattle herds.<sup>82</sup> The concern over British food was compounded by the 2001 outbreak of foot-and-mouth disease. The number of animals affected was around 3,500,<sup>83</sup> and ten million animals (seventeen percent of all U.K. livestock) were slaughtered in the subsequent preventative cull.<sup>84</sup>

Finally, the national supply of blood products in the United Kingdom is suspected of being generically infected. The first high-profile wave of infection was

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the House of Commons for the Report Evidence and Supporting Papers of the Inquiry into the Emergence and Identification of Bovine Spongiform Encephalopathy (BSE) and variant Creutzfeldt-Jakob Disease (vCJD) and the Action Taken in Response (Oct. 2000), *available at* <http://www.bse.org.uk/report/index.htm> (last visited May 6, 2002).

74. Council Directive 1999/34/EC, 1999 O.J. (L 141) 20-21. On the exemption, see STAPLETON, *supra* note 16, at 303-05.

75. *Mad Cow-Like Disease Spreads Rapidly in Wild Deer*, ENVTL. NEWSNETWORK, Oct. 1, 2001; David Osborne, *Elk Get Blame as US is Hit by CJD Scare*, INDEP. (London), Jan. 21, 2001.

76. Joseph B. Verrengia, *Disease Prompts Slaughter of Elk, Deer Herds*, SEATTLE TIMES, Mar. 17, 2002, at A7.

77. *Id.*

78. Charles Clover, *Vets to Test Wild Animals for 'Mad Deer Disease'*, DAILY TEL. (London), May 3, 2001.

79. David Osborne, *'Mad Cows' May Have Reached Midwest*, INDEP. (London), Jan. 15, 2001.

80. *Danger of Eating Out*, DAILY EXPRESS (London), Jan. 10, 2002; *Rise in Food Poisoning Cases*, DAILY TEL. (London), Feb. 12, 2002.

81. Richard Alleyne, *Poisonous Bacteria Found in Half of All Chickens Sold*, DAILY TEL. (London), Aug. 17, 2001.

82. Leake, *supra* note 48, at 5G.

83. Charles Clover & Sandra Barwick, *Foot and Mouth Epidemic is World's Worst*, DAILY TEL., (London), Sept. 4, 2001.

84. Robert Uhlig, *10 Million Animals Were Slaughtered in Foot and Mouth Cull*, DAILY TEL. (London), Jan. 23, 2002. It is of interest that while the cost of the foot-and-mouth outbreak was £2 billion, £1.2 billion of this is being claimed from E.U. See Melissa Kite, *TIMES* (London), Nov. 23, 2001, at 1.

by the HIV virus. This was followed by a wave of Hep C infection. The impact of these disasters on the U.K. hemophiliac population of 5,000 is illustrative: their use of infected blood products during the 1980s resulted in 1,200 contracting HIV of whom 800 have died,<sup>85</sup> and 4,800 contracting Hep C of whom more than 110 have died.<sup>86</sup> In the United Kingdom, virtually all hemophiliacs who are presently over the age of fifteen are infected with HIV, Hep C, or both.<sup>87</sup> To date, Australia, Belgium, Canada, Germany, Hong Kong, New Zealand, Switzerland, and the United States have banned blood donations by people who had lived in the United Kingdom during the BSE/CJD outbreak.<sup>88</sup> Of course, the United Kingdom cannot impose a similar ban on its domestic donors.

## VII. RESPONSE OF THE RESTATEMENT THIRD

By omitting any substantive discussion in its text, the *Restatement Third* suggests that, apart from blood infection cases, the United States has had no significant case law experience with generic infection cases formulated as products liability claims. In addition, in the blood infection cases, the consensus seemed to be that it was too difficult to accommodate them coherently within the U.S. products liability rule.<sup>89</sup> In other words, the U.S. rule could not both extend to such cases and accommodate an adequately convincing explication of the policy and moral issues at stake. These cases had, after all, led to the widespread adoption of "blood shield" statutes in most states.<sup>90</sup> But, if we were to speculate upon what

85. DAILY TEL. (London), Nov. 11, 2001.

86. Helen Studd, *Hepatitis Cases Land NHS With £10m Bill*, TIMES (London), Mar. 27, 2001, at 5L. In the United States, half the haemophiliac population contracted HIV or Hep C from blood products. Conk, *supra* note 19, at 1090.

87. See *supra* note 64. Compare the U.K. experience with the Hep C disaster in Canada. According to Michael Trebilcock et. al., *Do Institutions Matter? A Comparative Pathology of the HIV-Infected Blood Tragedy*, 82 VA. L. REV. 1407, 1485-86 (1996), it was conservatively estimated in 1996 that there are 100,000 people in Canada infected with Hep C, the current per unit risk of blood for Hep C is one in 40,000, as many as 12,000 people may have been infected with Hep C between 1986 and mid-1990 when screening began in Canada, and that seventy percent of Canadian hemophiliacs over the age of seven are infected with Hep C. In Canada, class actions related to infection with Hep C from blood precipitated a settlement of \$1.5 billion (Canadian). Garry D. Watson, *Class Actions: The Canadian Experience*, 11 DUKE J. COMP. & INT'L L. 269, 282-83 (2001).

88. See Patrick Barkham, *Australia Bans Blood of Travellers to UK*, GUARDIAN (Aus.), Sept. 22, 2000; *Blood Ban*, SUNDAY TIMES (Canada), July 18, 1999, at 26; Jill Carroll, *Tighter Blood-Donor Rules Are Backed To Fight Spread of Mad-Cow Disease*, WALL ST. J., June 5, 2001, at B4. The bans apply to those who spent more than six months in the United Kingdom between 1980 and 1996. *Id.*

89. Even under a negligence theory, plaintiffs have typically failed. See Christopher DeMayo, *Malpractice: Alaska Supreme Court Limits Duty of Hospitals to Disclose Risks of Blood Transfusions*, 26 J.L. MED. & ETHICS 252, 252 (1998) (discussing a holding that there existed no duty to warn of risk of Hep C from transfusion); George W. Conk, *The True Test: Alternative Safer Designs for Drugs and Medical Devices in a Patent-Constrained Market*, 49 UCLA L. REV. 737, 773-74 (2002) [hereinafter *The True Test*].

90. See DAN B. DOBBS, *THE LAW OF TORTS* 979-980 (2000). But see Conk, *supra* note 19, at 1091-1101 (staging a bracing attack on the protective attitude of blood shield statutes). For cases that succeeded despite these laws, see R. Jo Reser & Barbara A. Radnofsky, *New Wave of Tainted Blood*

approach to pathogenic infection cases would be taken under the *Restatement Third*, we would find it highly fractured according to the type of product:

- (1) If the infection was contracted from human blood or human tissue, the *Restatement Third* provides no redress;<sup>91</sup>
- (2) If the infection was contracted from a vaccine, the case would be decided under § 6, which provides special protection to defendants;<sup>92</sup>
- (3) If the infection was contracted from food, the case would be decided under § 7, which would only provide recovery on the basis of the consumer expectations test, namely if a reasonable consumer would not expect the food to contain that infection. Even within this class, as we will see, the case law divides incoherently between sub-classes;<sup>93</sup>
- (4) If the infection was contracted from other products, such as leather or woolen clothing, the case would be decided under § 2. Even here, the treatment is explicitly fractured according to how we classify the product condition:
  - (a) If the product condition is classified as a “manufacturing defect” case, just as infected raw material cases are currently classed (on the basis that the condition of such infected products departs from their intended easily-known design), recovery would be possible without further proof of defect, a “reasonable alternative design” (RAD) or fault.
  - (b) If the product condition is classified as a design/warning case (on the basis that the artificial manufacturing process did not introduce the problem), defectiveness would be determined by the cost-benefit/reasonableness principle and the RAD requirement.

Of course, this odd fragmentation prompts the question of why the *Restatement Third* differentiates between product types at all.<sup>94</sup> Perhaps, when a new legal rule emerges without a well-conceived theoretical basis, as was the case with the

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*Litigation: Hepatitis C Liability Issues*, 67 DEF. COUNS. J. 306 (2000). Interestingly, the blood shield statutes followed an epidemic of transfusion-associated Hepatitis in the mid-1960s. See Conk, *supra* note 19, at 1098-99 (arguing that statutes’ enactment led to the continuing transfusion infections in the decades that followed). “The blood shield laws thus allowed the blood industry to continue to make blood products that were avoidably unsafe. . . .” *Id.* at 1100.

91. RESTATEMENT THIRD, *supra* note 7, § 19(c).

92. *Id.* § 6. See also James A. Henderson, Jr. & Aaron D. Twerski, *Drug Designs Different*, 111 YALE L.J. 151 (2001) [hereinafter *Drug Designs*] (rebutting Conk’s criticism of the *Restatement Third*).

93. See *infra* note 95 and accompanying text.

94. See Conk, *supra* note 19, at 1088-90 (attacking the “special, protective standard” given to prescription drugs and medical devices in § 6).



*Restatement Second*, courts are tempted to give the rule “structure” by compartmentalizing fact situations. In theory, if not in practice, it is very easy to distinguish cases of infection from eating meat and cases of infection from wearing infected clothing. The problem is that the law has no compelling reason to make the distinction—quite the contrary.

Consider the position of five different people who have contracted CJD from five different classes of BSE-infected products. Whatever the product vehicle for the infection, there is a very strong argument that the moral, deterrence, and other socio-legal concerns, which are common across all five cases, swamp any special factor relating to a particular product type. This is also true within a product class. For example, the incoherence of the treatment of infected food cases in the United States already highlights this flaw in the structure of the U.S. regime; food which happened to be classed as “adulterated” by infection is treated under a manufacturing errors framework, but food which happened to be classed as “inherently infected” is treated more like a design case.<sup>95</sup>

Infection cases also illuminate the central absence of a rationale for the *Restatement Third* regime—namely, its attempt to treat manufacturing errors separately. Why are manufacturing errors treated differently from other product conditions in *Restatement Third*? The origin of the special regime for products liability is traditionally recognized as having drawn its features from both warranty and tort. However, warranty does not provide a foundation for the special treatment of manufacturing errors in our modern separate product regimes.

It is true that, for more than a century before the *Restatement Second*, courts allowed plaintiff-buyers to succeed in warranty claims against a product supplier even though the relevant product condition, such as infection in milk, was undiscoverable.<sup>96</sup> This warranty liability was, therefore, clearly strict. Moreover, these “classical” warranty claims were just as available in relation to a product design and were just as strict. The reason that this strict-liability-for-design norm did not prove unworkable was that a warranty claim only succeeded if the product failed in one of its intended uses. In other words, classical warranty cases were effectively ring-fenced by the requirement that the plaintiff prove the product had “failed in its intended use.” This was a requirement a plaintiff could rarely meet in a *design* case because, in virtually every case, the manufacturer would have at least tested his design to ensure it did what it was supposed to do. This meant that there was no need or rationale for warranty law to distinguish manufacturing from design cases. Both could be kept within bounds. Strict liability could be imposed on both.

Rather, it was from the negligence side that the special treatment of manufacturing errors originated. To many observers, negligence courts seemed to have ratcheted up the standard of care in manufacturing error claims, though the

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95. See Stapleton, *supra* note 45.

96. See *Frost v. Aylesbury Dairy Co.*, 1 K.B. 608, 610 (C.A. 1905).

requirement of fault was never explicitly abandoned.<sup>97</sup> In time, this treatment led to the widespread conclusion that the law, in effect, imposed covert strict liability for manufacturing errors, albeit under the guise of the tort of negligence. In the United States, recognition of a separate products rule in tort in the 1965 *Restatement Second*, aimed to regularize this perceived masking of a pocket of strict liability. So, what we now have in the *Restatement Third* is a regime where a product with a manufacturing error, *even if the error is unforeseeable*, by definition is defective. This is real strict liability for manufacturing errors. In contrast, a product with a dangerous design condition, if the danger is unforeseeable, cannot, *by definition*, be defective. Liability for design is not strict, but is based on and bounded by reasonableness.

As Appendix B shows, premanufacture generic infection cases share factual characteristics with both the traditional classification of manufacturing defects cases and the traditional classification of design cases. This means that, before we can successfully classify premanufacture generic infection cases as one or the other, we need to be clear about what factual characteristics we have used to distinguish types of product condition and to be clear about the normative basis for drawing distinctions based on those characteristics. The Reporters define “manufacturing defect” as the product departing from its intended design.<sup>98</sup> Infected products certainly depart from what the manufacturer *hoped* the product condition would be, but the manufacturing process did not *introduce* the danger. It follows that if the reason we subject manufacturing errors to strict liability is embedded in the idea that the danger was introduced into the product by the artificial process of manufacture, premanufacture generically infected products would fall outside the classification of “manufacturing errors” and therefore outside strict liability treatment. The absence of an agreed-upon rationale for the imposition of strict liability on manufacturing error conditions is reflected in the incoherence of U.S. case law on isolated infected products. Remarkably, this theoretical void exists even though these were the product conditions that were at the very heart of the new tort rule set out in the *Restatement Second*.<sup>99</sup>

We still have no principled explanation of why, for example, it is fair to hold a manufacturer strictly liable for some product flaws he could not discover (for example, some manufacturing errors), but not fair to do so in relation to a different set of product flaws he could not discover (namely, unforeseeable design dangers).<sup>100</sup> We have never clarified whether the normative motive for a harsher

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97. I have yet to find a case based on a claim in the tort of negligence where the imposition of strict liability could be the only explanation for the result. For example, I have been unable to find a case where liability was imposed even though all parties agreed that the relevant risk was completely unforeseeable. Of course, if such a case did exist, it could only be explained on the basis of strict liability, because it is not possible to be careless in relation to a risk that is unforeseeable.

98. RESTATEMENT THIRD, *supra* note 7, § 2(a).

99. See Stapleton, *supra* note 45.

100. Of course, even in negligence, we tolerate significant pockets of liability that is strict—the objective standard of care, recovery for “unforeseeable” consequences of breach, and unforeseeable eggshell skulls. There can be reasons for strict liability—for example, technology-forcing, loss

attitude to manufacturing errors stems from a *specific*, albeit unexpressed, rationale concerning the distribution of risks associated with dangerous conditions introduced into products by artificial manufacturing processes. Additionally, we have never clarified whether the pragmatic argument in favour of strict liability for manufacturing errors, namely the availability of the production line norm, requires the departure from that norm *be due to* the failure of the production system. Case law experience on both sides of the Atlantic, even in cases of isolated infected products, gives little conceptual or pragmatic guidance on these crucial questions. This gap means it is not possible to determine from first principles how and why we should classify premanufacture generic infection cases.

In short, infection cases highlight both the absence of any fundamental rationale for the traditional tri-fold classification of product defects and suggest that it is unlikely for there to be any agreement on where and why such lines should be drawn before a full debate on the issue has occurred. A recent high-profile academic debate has unwittingly confirmed these points. In 2000, George Conk launched a scathing attack on how the *Restatement Third* had, under § 6, given especially protective treatment to prescription drugs and medical devices.<sup>101</sup> As an exemplar of the problems he argued would be created by § 6, Conk referred to the alleged “design defect” in blood infected with Hep C.<sup>102</sup> In their response article, the Reporters attempted to rebut this classification by merely asserting that “[t]he plaintiffs in the blood cases did not claim that the blood products that harmed them were defectively designed. . . . Instead, the contaminants that caused their harm constituted manufacturing defects. . . .”<sup>103</sup> Conk’s otherwise powerful reply seems just as ad hoc on the classification point:

The basic distinction between a manufacturing defect and a design defect is that the former departs from the manufacturer’s specifications and intentions for the product. A claim of design defect attacks the manufacturer-designer’s product concept or its failure to adopt specific safety measures. . . .

This “departure from its intended design” definition of a manufacturing defect underlies my categorization of the defect in [the blood product] as one of design. . . . [V]iral contamination was not a flaw, a departure from design expectations, or even from consumer expectations, but rather was considered an “acceptable risk,” one left by the manufacturers to their customers’ physicians to manage medically. Decisions on whether. . . to flameproof fabrics are considered product design

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spreading, superior information of the defendant, proof problems—but what we do not have is a reason substantial enough to delineate and defend the boundaries of this special pocket of strict liability for products from the general law of negligence.

101. Conk, *supra* note 19, *passim*.

102. *Id.* at 1112.

103. *Drug Designs*, *supra* note 92, at 160.

choices . . . . The defect in [the blood product] was neither an unintended departure from manufacturer's specifications, nor a disappointed consumer expectation defect like botulism in improperly canned food, but rather one of design. . . .

Every batch of the concentrated blood proteins was made without departure from its intended design. The hemophiliacs' product liability claims, therefore, were not for manufacturing defects. Rather, the hemophiliacs . . . correctly alleged design defects, citing failure to market a practical and feasible alternative safer design.<sup>104</sup>

### VIII. RESPONSE OF THE DIRECTIVE AND ITS CLONES: THE PROBLEM OF THE EUROPEAN COMMISSION AND THE "OFFICIAL" RECORD

Does the Directive provide a clearer resolution of the anomalous treatment of manufacturing errors that premanufacture generic infection cases expose? Certainly the Directive has no confusing fracturing around the classification of the product type. There is also no explicit classification based on type of product defect. Moreover, in the general law of the EU and its Member States, there are no laws shielding certain entities, such as blood banks, no equivalent doctrine of federal preemption under which so many U.S. infection claims can be held to be barred, and no general tort immunity for state entities.<sup>105</sup> On the other hand, unlike in the U.S. regimes,<sup>106</sup> under the Directive, a party cannot sue for physical loss to its commercial property.<sup>107</sup> This means, for example, that the claims against cattle feed producers currently being made by French farmers whose stock has allegedly contracted BSE from the feed cannot be brought under the Directive.<sup>108</sup>

Finally, it is significant that under the Directive a product condition may qualify as a defect under Article 6, but not attract liability because it was undiscoverable at the time of circulation and so triggers the development-risk defence in Article 7(e). In contrast, under § 2(b) of the *Restatement Third* the undiscoverability of a design flaw prevents the product from even qualifying as defective.

As Appendix C shows, products case law under the Directive and its clones is very thin. Importantly, European case law concerning infected products is just as

104. *The True Test*, *supra* note 89, at 772-73 (citations omitted).

105. *See, e.g., Boulahanis v. Prevo's Family Mkt., Inc.*, 583 N.W.2d 509, 509 (Mich. Ct. App. 1998) (holding the claims of consumers who were made sick (one died) by beef infected with E Coli 0157 were preempted by the Federal Meat Inspection Act); *cf. Smith v. Secretary of State for Health* (Q.B. Feb. 15, 2002) (Morland, J.), *available at* <http://www.lexis.com> (concerning a negligence claim against the government agency which regulates medicines by child whose Reye's Syndrome was triggered by aspirin).

106. David A. Fischer & William Powers, Jr., *PRODUCTS LIABILITY: CASES AND MATERIALS* 567 (2d ed. 1994); *RESTATEMENT THIRD*, *supra* note 7, § 21 cmt. e.

107. Directive, *supra* note 3, art. 9.

108. *See Martyr*, *supra* note 11, at 14. The U.K. exported potentially contaminated feed to sixty-nine countries. *French Ministries are Raided in BSE Inquiry*, INDEP. (London), Jan. 18, 2001.

incoherent as infected product case law in the United States, though for different reasons. The principal case, at least of those available in English, is *In Re Hepatitis C Litigation (A v. National Blood Authority)*.<sup>109</sup> Here 114 British claimants sued the National Blood Authority (NBA) over Hep C infection from blood products.<sup>110</sup> When the trial judge, Justice Michael Burton, looked at the idea of defect in Article 6 of the Directive, he rightly noted that the words in “all relevant circumstances” must be read in the light of the statutory purpose.<sup>111</sup> But, as we have seen, there was no coherent and consistent statutory purpose behind the Directive. It was a political fudge that tried to square a circle. It used the rhetoric of strict liability and yet seemed to protect reasonable businesses in Article 6(2) and 7(e).<sup>112</sup>

An added problem for the trial judge was that a large proportion of the historical record available to the court consisted of papers from the European Commission, which unlike conventional Westminster-style bureaucracies, is not obliged to provide neutral advice to the EU institutions. In particular, it could well be argued that the role of the European Commission prior to the Final Directive of 1985 was highly partisan.

It is well known that the Thalidomide tragedy focused, and perhaps unduly mesmerized, European attention on cases of generic product conditions. But it is inaccurate to conclude that all European countries wanted strict liability imposed on manufacturers, even if it was limited to cases of personal injuries. No Member State ratified the 1977 Convention of the Council of Europe,<sup>113</sup> which contained just such a regime. Another reason Member States failed to ratify the (non-EC) Convention was that, as we have seen,<sup>114</sup> within the European Communities political concern arose in the late 1970s to give the European Communities a “human face,” to show, for example, that it had consumers’ interests at heart as well as being concerned with the facilitation of a level playing field for business.<sup>115</sup> However, Member States were firmly divided on the substantive content of any

109. 3 All E.R. 289 (Q.B. 2001). The author of this Essay acted as Consultant to the defendants in this case.

110. *Id.* Though this was a group action, it was also a “test” case for the 3,000-5,000 people in the United Kingdom who have contracted Hep C from transfused blood and blood products. In the United States, there are about 2.7 million persons chronically infected with HCV. Miriam J. Alter et al., *The Prevalence of Hepatitis C Virus Infection in the United States, 1988 Through 1994*, 341 NEW ENG. J. MED. 556, 556 (1999). Before 1990, 300,000 people received blood products and are therefore at risk of having been infected with Hepatitis C. Reser & Radnofsky, *supra* note 90, at 317. In the United Kingdom, most health care is delivered under the National Health System (NHS). The supply of goods and services under the NHS is free at the point of delivery, and there is no contractual relationship between the patient and any party within the delivery system.

111. *In re Hepatitis C Litig.*, 3 All E.R. at 290.

112. Directive, *supra* note 3, arts. 6(2), 7(e).

113. Council of Europe, *European Convention on Products Liability in Regard to Personal Injury and Death*, (Strasbourg, Jan. 27, 1977) available at <http://conventions.coe.int/treaty/en/Treaties/Html/091.htm> (last visited May 6, 2002).

114. See *supra* note 29 and accompanying text.

115. STAPLETON, *supra* note 16, at 47-48; Frank A. Orban, III, *Product Liability: A Comparative Legal Restatement—Foreign National Law and the EEC Directive*, 8 GA. J. INT’L & COMP. L. 342, 374 (1978).

new Directive on products liability.

The result of the protracted and often grossly secretive negotiations,<sup>116</sup> a result not achieved until 1985, was a Directive with a cryptic text that even the European Court of Justice, the highest court in the EU, has attacked as hard to interpret.<sup>117</sup> A major danger when approaching the interpretation of the text is the past attitude of the Commission. Throughout the 1970s, the Commission embraced a strong preference for an unqualified strict liability being imposed on manufacturers for injuries due to the condition of their product. This is reflected in the fact that neither of the Commission's draft Directives (1976 and 1979)<sup>118</sup> mention any exculpatory ideas couched in terms of "state of the art" or "development risks." Yet, there was intense concern within the European Parliament and the Council that substantial exculpatory provisions should be included.<sup>119</sup> For example, the official Economic and Social Committee (ECOSOC), that represents sectional interests (mostly workers)<sup>120</sup> and advises the Commission and the Council, maintained that industry should not be made "liable for products which could not have been made to a safer standard at the time when they were put into circulation" and specifically noted that "it may be in the patients interests to put into circulation products which are known to have side-effects when taken by some or indeed all persons."<sup>121</sup> The same concern prompted other EU institutions to make two critical exculpatory changes to the Commission's proposed text. One was the inclusion in the Article 6<sup>122</sup> definition of defect, not merely of the time qualification that a relevant factor was "the time when the product was put into circulation," but the statement that "a product shall not be considered defective for the sole reason that a better product is subsequently put into circulation;" the second was the inclusion of the development-risk defence in Article 7(e) with an option for an individual Member State to exclude that defence.<sup>123</sup> The Commission's continued opposition to such pro-defendant amendments was deeply resented by some Members of the European

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116. On the secrecy of the Council's deliberations, see Commission's Written Answer to Question No. 1152/84.

117. Case C-300/95, *Comm'n v. United Kingdom*, 1997 E.C.R. I-2649, [1997] All E.R. 481 (providing a report which includes both the judgment of the European Court of Justice (ECJ) and the advice given to the Court in the previous Opinion of the Advocate General (Jan. 23, 1997) (G. Tesaurro) that reached the same conclusion via a somewhat different route).

118. See First Draft Directive, *supra* note 31, at 9; Second Draft Directive, *supra* note 31, at 3.

119. See *supra* note 32.

120. PAUL CRAIG & GRÁINNE DE BÚRCA, EC LAW 89-90 (1995).

121. ECOSOC Report, *supra* note 32, at 41-45.

122. See *supra* note 34 and accompanying text.

123. Directive, *supra* note 3, at 29-33. See Kathleen M. Nilles, Note, *Defining the Limits of Liability: A Legal and Political Analysis of the European Community Products Liability Directive*, 25 VA. J. INT'L L. 729, 754 (1985) (describing how it was the Council's Permanent Representatives Committee (COREPER) in February 1982 and not the Commission that formulated the route to the final 'options' compromise, abandoning the absolute position on development risks adhered to by the Commission); see also Amended Proposal from Presidency of Council (Apr. 26, 1985), which sought to accommodate the position of six delegations opposed to liability for development risks. These were not the only points on which the Commission was defeated. For example, there was an insertion of option concerning an exemption for unprocessed agricultural products.

Parliament. For example, in debate one Member accused the Commission of misleading the European Parliament in order to get the Commission's pro-plaintiff product liability proposals accepted while another complained that the European Parliament's proposals were "arbitrarily changed by the Commission."<sup>124</sup>

The Commission's attitude seemed to be the result of three factors. First, at the outset, the Commission asserted, at least in public, that Member States genuinely were willing and committed to providing a legal entitlement to compensation to those in the future who found themselves in the equivalent position of the Thalidomide children. This necessitated the imposition of genuine strict liability, at least for unforeseeable generic design conditions. Secondly, the Commission shared a common crude misconception, circulating in Europe in the 1970s, that the common law in the United States had successfully adopted genuine strict liability for products merely by making producers liable on proof that the plaintiff had been injured by a "defect" in the product.<sup>125</sup> Of course, the actual position was very different and less impressive. The reformists behind § 402A of the *Restatement Second*<sup>126</sup> were centrally concerned only with manufacturing errors. Here the notion of "defect" seemed unproblematic because it could be, it was thought, conveniently determined by the production line norm. Later events revealed that § 402A failed to address the sort of claims that were to trouble the legal regimes in the United States (classic design cases) and Europe (allegedly unforeseeable generic conditions). Thirdly, the Commission seemed to think that the notion of defect could be deployed independently of an evaluation of the "appropriate" or "reasonable" level of safety to be required of a product. This crudely sanguine attitude cannot withstand the most elementary consideration of classic design cases such as a claim that a chair or axle was "not strong enough."<sup>127</sup>

By the time of the adoption of the Final 1985 Directive, it was clear that the U.K. Government would only agree to a Directive that gave industry the capacity to answer a claim on the basis that it had done all it realistically could and should have done to make the product safe in all the circumstances.<sup>128</sup> Other demands by

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124. See EUR. PARL. DEB., 1980-1981 O.J. (Annex 1-256) 261, 293 (1980), quoted in the excellent study of the Directive's history by Nilles, *supra* note 123, at 753, n.143, 754, n.146; see also Nilles, *supra* note 123, at 757-58 (blaming the slow progress on the agreement of a Final Directive on, *inter alia*, the intransigence and the lack of rigour by the Commission that polarized interested parties); The Lord Griffiths et al., *Developments in English Product Liability Law: A Comparison with the American System*, 62 TUL. L. REV. 353, 389 (1988) (concerning the strong opposition of the European Parliament to the inclusion of liability for development risks in the Commission's drafts).

125. See, e.g., Hans Claudius Taschner, *Product Liability in Europe: Future Prospects*, in EEC STRICT LIABILITY IN 1992 81, 89 (P.L.I. ed., 1989): ("[T]he concept of defect has not caused any practical difficulties for courts throughout the world.").

126. RESTATEMENT SECOND, *supra* note 7, § 402A.

127. See *supra* notes 20-24 and accompanying text.

128. The British Minister for Consumer Affairs noted the United Kingdom's insistence on "the incorporation of the 'state of the art' defence." See 991 PAD. DEB., H.C. (5th Ser.) col. 1107 (1980); see also *id.* at cols. 1106-1200; DEPARTMENT OF TRADE AND INDUSTRY EXPLANATORY MEMORANDUM OF EUROPEAN COMMUNITY LEGISLATION (1985). "[The 1979 Commission draft Directive] was not acceptable. One of the most important changes to be sought was the incorporation of a 'state of the art' defence. This is now incorporated in the proposed [Final] Directive." *Id.* ¶ 11. "The standard [of

Member States ensured the final text of the Directive was a political “fudge” that tried to square the circle of disagreement between Member States by use of ambiguous terms and a cryptic text. Most importantly, other Member States acquiesced in the attachment—to the Council’s decision on the Directive—of a number of Unilateral Statements by individual delegations, including a *Unilateral Statement by the United Kingdom Delegation on Article 7(e)* which stated:

This provision should be interpreted in the sense that the producer shall not be liable if he proves that, given the state of scientific knowledge at the time the product was into circulation, no producer of a product of that kind could have been expected to have perceived that it was defective in design.<sup>129</sup>

The whole purpose of the insertion, against the wishes of the Commission, of the exculpatory defence in Article 7(e), as well as the time dimension introduced into the notion of defect in Article 6, was to give a substantial protection to industry, particularly new and innovative industries. Yet, even after the adoption of the 1985 Directive with these provisions, Hans Claudius Taschner,<sup>130</sup> a principle member of the Commission’s products liability team, maintained that the correct interpretation of the Directive was one that gave little, if any room, for defendants to exculpate themselves from liability.<sup>131</sup>

The political reality is that the Thatcher Government used its EU legislative veto to insist on protection for a producer who had done all it realistically could and should have done to make the product safe in all circumstances. More generally, the

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defectiveness] should be determined objectively having regard to all the circumstances in which the product was put into circulation . . . [and] a product shall not be considered defective for the sole reason that a better product is subsequently put into circulation.” *Id.* ¶ 13. “Both the House of Commons and industry consider [the development risks] defence as a *sine qua non* for their agreement to the Directive. It is now included in the proposed [Final] Directive.” *Id.*

129. *Note Point “A” au Conseil (8205/85): Statements To Be Entered in the Council Minutes* ¶ 7 (July 23, 1985).

130. Sometime Head of Division, Directorate General for Internal Market and Industrial Affairs, European Commission; Adviser to the Hep C claimants.

131. Concerning the risk in the Thalidomide case, Taschner claims it was not “absolutely unforeseeable” and so was not a true example of a development risk for which liability was removed by Article 7(e). Hans Claudius Taschner, *European Initiatives: The European Communities, in* COMPARATIVE PRODUCT LIABILITY 1, 6 (C.J. Miller ed., 1986) (claiming that the opposite was “wrongly considered by the two British Law Commissions”). Since, he asserts, the criterion for development risk is that the “existing defect could not be discovered by anyone,” Taschner’s view is that Article 7(e) would not protect the producer in a new Thalidomide-like disaster. *Id.* at 11; *see also* Hans Claudius Taschner, *Harmonization of Products Liability Law in the European Community*, 34 TEX. INT’L L.J. 21, 32 (1999) [hereinafter *Harmonization of Products Liability Law*]. In contrast to Taschner, most commentators consider that Article 7(e) would protect the defendant in such cases. *See* Aubrey L. Diamond, *Product Liability and Pharmaceuticals in the United Kingdom*, in CONSUMER LAW IN THE EEC 129, 135 (G.F. Woodroffe ed., 1984) (citing the view of the Pearson Commission at ¶ 1259); Christopher Newdick, *Strict Liability for Defective Drugs in the Pharmaceutical Industry*, 101 L.Q. REV. 405, 408 (1985); M. Griffiths, *Defectiveness in EEC Product Liability* 1987 J.B.L. 222, 227; PARL.DEB. (H.L.) col.1455 (1980) (Lord McKay of Clashfern).



literature on the status of Unilateral Statements from Member State delegations is thin. This is odd given that their existence exposes the political controversies to which they bear witness. It is also odd given the potential political storm that may flow by any crude enforcement of a rule that Unilateral Statements should not be considered in determining the appropriate interpretation of the EU instrument.<sup>132</sup> Certainly, an argument can be made that unless the European Court of Justice is willing to imply that the other Member States acted in bad faith in acquiescing to the U.K.'s Unilateral Statement, the Directive should be read, at least by U.K. courts, in the light of the U.K.'s Unilateral Statement and the clear demands of the United Kingdom for a substantial defence for industry. This was, after all, a Directive that *explicitly* gave considerable latitude to Member States to achieve local variations in the regime it sets up. Indeed, this political reality seems to be what lay behind the fairly cryptic European Court of Justice judgment in favour of the United Kingdom in *European Commission v. United Kingdom*,<sup>133</sup> which Taschner has attacked as "misunderstanding" the Directive.<sup>134</sup> The European Court of Justice held that the development-risk defence in Article 7(e) would succeed if the knowledge of the defect existed but was not "accessible."<sup>135</sup> The liability regime demanded by the United Kingdom would also require similar "reasonableness" glosses on other issues such as whose ideas were relevant to "knowledge."<sup>136</sup>

In short, official EU papers describing the Commission's pre-1985, pro-plaintiff vision for the content of a products directive and later comments by Taschner do not in any way capture the true compromise finally adopted in the text of the Directive. They fail to address the profound implications for the defect notion of the insertion of the time clause in Article 6 and the dilemma of how to determine defectiveness in design or warning, such as the classic design cases of the chair and axle, without the consideration of notions of behaviour and reasonableness. Commission documents also afford Article 7(e) a width so narrow and nugatory that they could suggest the United Kingdom was deceived by the other Member States in the meaning of the alleged agreement to the Final Directive. Yet it seems that Commission documents available to the court in the Hepatitis C case far outnumbered any official papers opposed to Commission proposals. These are

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132. See, e.g., Joined Cases C-283/94, C-291/94 & C-292/94, *Denkavit Int'l BV, VITIC Amsterdam BV, Voormeer BV v. Bundesamt für Finanzen*, 1996 E.C.R. I-5063 at ¶28 (acknowledging that a substantial group of Member States had believed that "when the Directive was being adopted by the Council, it was agreed that relatively vague terms should be used in order to allow for differing interpretations according to the requirements of the domestic legal systems"); see also Jan Klabbers, *Informal Instruments Before the European Court of Justice*, 31 COMMON MKT. L. REV. 997, 1008-09 (1994) (discussing reliance on Member States Declarations in legislation minutes); Sir William Nicoll, 'Note the Hour—and File the Minute,' 31 J. COMMON MKT. STUDS. 559, 561 (1993) (stating that "[d]eclarations have no legal value, but they offer some insight into the intentions of the parties").

133. Case C-300/95, *Comm'n v. United Kingdom*, 1997 E.C.R. I-2649, [1997] All E.R. 481.

134. *Harmonization of Products Liability Law*, *supra* note 131, at 34.

135. Case C-300/95, *Comm'n v. United Kingdom*, 1997 E.C.R. I-2649, [1997] All E.R. 481. See Taschner, *supra* note 131, at 34.

136. Jane Stapleton, *Products Liability in the United Kingdom: The Myths of Reform*, 34 TEX. INT'L L.J. 45, 59 (1999).

critical points for addressing the dilemma of what is to be taken as the statutory purpose of any EU Directive.

#### IX. RESPONSE OF THE DIRECTIVE AND ITS CLONES: THE HEPATITIS C JUDGMENT

In the Hepatitis C case, the court noted that the Directive “must be construed by reference to its recitals and indeed to its legislative purpose, insofar as it can be gleaned otherwise than from the recitals.”<sup>137</sup> The court asserted in a number of places that “the purpose of the Directive is to achieve a higher and consistent level of consumer protection throughout the Community and render recovery of compensation easier, and uncomplicated by the need for proof of negligence.”<sup>138</sup> Yet the court gives little if any weight to Recital 7, which states a purpose of the Directive was to vindicate the notion that a “fair apportionment of risk between the injured person and the producer implies that the producer should be able to free himself from liability if he furnishes proof as to the existence of certain exonerating circumstances.”<sup>139</sup>

Similarly, the court neglects two important political facts: the United Kingdom’s Unilateral Statement and the fact that the European Parliament and Member States successfully insisted, against the opposition of the Commission, on the inclusion of exculpatory provisions to achieve that “fair apportionment.” Moreover, the court marginalizes the important legal fact that, when in *European Commission v. United Kingdom*,<sup>140</sup> the European Court of Justice read into the Directive extra concerns, they were ones that provided exculpation for defendants. Finally, the court ignored the phenomenon well-known among comparative lawyers that—in contrast to the “candour” of pragmatic regimes such as that in England, Scotland, and the Netherlands—courts in certain continental legal systems use “hidden and indirect means of controlling” liability arising from the formal statement of broad entitlements.<sup>141</sup> This phenomenon is obviously relevant to properly “domesticating” an EU provision couched in vague terms.

In short, the court in the Hepatitis C case was determined to give the Directive “work to do” in the United Kingdom;<sup>142</sup> that is to give it a wider ambit of entitlement than existed elsewhere in the English law of obligations. It was eager to avoid a construction that would “not only be toothless but pointless.”<sup>143</sup> The trial judge seems to have thought this required an adoption of the construction urged by

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137. *In re Hepatitis C Litig.*, 3 All E.R. 289, 305 (Q.B. 2001).

138. *Id.* at 310-11; *see also id.* at 328 (stating that the purpose of the Directive was “consumer protection and ease of recovery of compensation.”); *id.* at 342 (stating purpose was “to prevent injury and facilitate compensation for injury.”); *id.* at 341 (explaining analysis of Article 7(e) to achieve underlying purpose).

139. *Id.* at 304 (quoting Recital 7).

140. 1997 E.C.R. I-2649, [1997] All E.R. 481.

141. M. BUSSANI & V. PALMER, *THE FRONTIERS OF TORT LIABILITY: PURE ECONOMIC LOSS IN EUROPE*, 71, 152-53 (2002).

142. *In re Hepatitis C Litig.*, 3 All E.R. at 289.

143. *Id.* at 340.

the claimants. In my view, this was mistaken. For example, it would still be consistent with the pro-consumer purpose of the Directive, as selected by the judge, that the Directive was aimed merely at leveling up other Member States to the level of consumer protection already in place in the United Kingdom. In any case, the Directive *did* unequivocally make a number of improvements to the position of the U.K. consumer that did not require the court to adopt the claimants' construction.<sup>144</sup>

In my view, the "reformist zeal"<sup>145</sup> of the trial judge in the Hepatitis C case simply preferred the heroic rhetoric of the claimants' cause.<sup>146</sup> His decision has already faced academic criticism,<sup>147</sup> and there are certainly some very strange factual holdings and pieces of legal reasoning in it—most of which are not directly pertinent to the topic of this Essay. However, one core aspect of his approach is relevant here. To find in the claimants' favour, the trial judge created a new set of central concepts and then implied them into the Directive. Specifically, while he concludes that "there is no place . . . in the Directive" for the "American terms" of manufacturing defects, design defects, and instruction defects,<sup>148</sup> the trial judge himself read into the Directive distinctions based on type of product defect. Indeed, he constructed a whole new class of product conditions called "non-standard products" which covers not only manufacturing error cases but also covers premanufacture infection cases.<sup>149</sup> By then asserting that a nonstandard product was to be compared with the "standard" (that is intended, and hoped for) state of the product (namely one that was not infected), the judge arrived at the conclusion that the infected batches of blood had been defective.<sup>150</sup> The classification as "nonstandard" seems inexorably to lead to a finding of defect, at least if there has been no warning.

Though the defect provision, Article 6, stresses that "all the circumstances" are to be taken into account, the judge reformulates this as all the circumstances relevant to the purpose of the Directive. By this device and his focus only on the pro-consumer goals of the Directive as set out in its recitals, he excludes, as irrelevant to defectiveness, issues such as the avoidability of the dangerous condition,<sup>151</sup> the utility of the product line, whether safer substitutes were feasible

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144. Stapleton, *supra* note 136, at 61-62.

145. Geraint Howells & Mark Mildred, *Infected Blood: Defect and Discoverability. A First Exposition of the EC Product Liability Directive*, 65 MOD. L. REV. 95, 98 (2002).

146. *In re Hepatitis C Litig.*, 3 All E.R. at 289.

147. See Christopher Hodges, *Compensating Patients*, 117 L.Q. REV. 528 (2001) [hereinafter *Compensating Patients*]; Howells & Mildred, *supra* note 145, at 96-98; Simon Pearl, *Damaging Goods*, SOLICITOR'S J., May 11, 2001, at 424.

148. *In re Hepatitis C Litig.*, 3 All E.R. at 318.

149. *Id.* at 319. And product conditions classified "as a design defect resulting from a way in which the producer's system was designed." *Id.*

150. *Id.*

151. In my view, avoidability is not *necessarily* relevant, but can be when it is combined with the absence of available substitutes and high utility. For instance, what if a vaccine is developed that can immediately and permanently clear the HIV virus from the system of an infected fetus? The vaccine involves a risk of slight of hearing loss to one to three percent of affected fetuses but there is no test to prescreen which fetus will have its hearing damaged. The fetus cannot be warned, the utility of the vaccine is high (because there are no substitutes), and the cost risked is low. Yet according to the trial

and the cost of seeking to limit the risk, even if these factors are judged with hindsight. It goes without saying the judge also ignored the sort of public-policy concerns about the special importance of a blood supply that led to the blood shield laws in the United States.<sup>152</sup>

However, consider how this approach to the Directive would apply to “standard” products such as aspirin, an issue that is of immediate concern to the public. Even consumer advocates regard aspirin as nondefective despite the risk it poses to some users and the consumers’ unawareness of the risk.<sup>153</sup> On the one hand, the Hepatitis C court chose consistency and stated that utility should be ignored here just as it asserts it should be ignored when judging the defectiveness of nonstandard products.<sup>154</sup> But if we ignore the overall social utility of the standard product, which in the case of aspirin is universally acknowledged to be massive, how can aspirin’s nondefectiveness be established given that, from the perspective of the victim, its cost outweighed its benefit? The court’s attempt to bridge this gap in its approach is the mere assertion that “standard products, if compared at all, will be compared with other products on the market.”<sup>155</sup> But this is, of course, itself a *utility* measure: a product’s defectiveness being measured by any available substitutes on the market that have more successfully avoided the risk!<sup>156</sup>

What the Hepatitis C court seems to have done is extend the former class of “manufacturing errors” to include premanufacture infection cases, naming this new class “nonstandard” products. This extension does not avoid the unprincipled and anomalous treatment of a class of product conditions simply on the basis that they can be cheaply compared with a product condition that the producer hoped to produce, the so-called “standard” product. If aspirin can be judged nondefective even though it cannot be made safe for all users, why should nonstandard products that cannot be made safe for all users, but which have equivalent massive social benefits and low risk, be nondefective? This point is not academic but one of real practical importance.

Say a product is developed that immediately clears HIV infection from an infected fetus’s system but causes mild hearing loss in a percentage of those treated, and the state of scientific knowledge is such that this can neither be avoided nor the cases where this injury will occur be identified in advance. When the defectiveness of the product is being determined under the Directive, why should it matter if the product is a pure chemical preparation (like aspirin, a “standard” product) to which

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judge, these factors are not relevant to defect. *Id.* at 290.

152. *Compensating Patients*, *supra* note 147, at 530. The trial judge went on to hold, in relation to the defence in Article 7(e), that once risk of infection in a product sector was “known,” the development-risk defence was no longer available even if the dangerous condition was not discoverable in an individual product. *In re Hepatitis C Litig.*, 3 All E.R. at 305. This means that after the first victim’s claim, nonstandard products cannot attract the defence. *Id.*

153. *Howells & Mildred*, *supra* note 145, at 101.

154. *In re Hepatitis C Litig.*, 3 All E.R. at 339.

155. *Id.* at 319.

156. Directive, *supra* note 3, art. 6. Article 6 of the Directive, with its emphasis on time frame, strongly suggests that the existence or nonexistence of feasible substitutes was intended as relevant to the notion of “defect.” *Id.*

an undetectable percent of users is prone, or a vaccine derived from blood which has an undetectable infection in some percent of doses (like Factor VIII, a “non-standard” product)?<sup>157</sup> If, as the Community has said, one of its major aims is to promote competition and innovation, and if, as it has also said, “effective legal protection is a vital incentive for innovation,”<sup>158</sup> there seems to be some room for the argument that innovation leading to the development of one form of a HIV product should not be disproportionately inhibited. Yet this is exactly what is threatened by the approach taken by the Hepatitis C court.

My general point here is not that the decision in the Hepatitis C decision was necessarily wrong.<sup>159</sup> It is to show that, like the *Restatement Third*, the Directive does not accommodate premanufacture infection cases at all clearly because the entire regime lacks a coherent rationale. But whereas the failings of the *Restatement Third* stem from the over compartmentalization of doctrine and the neglect of discoverability issues, in Europe it was the incoherent political purpose of the Directive and its fudged terminology that has presented EU courts with the job of choosing the central norms on which it is to be read. Whichever side of the normative line one might choose, it is impossible to be confident that the text of the Directive delivers a clear vindication of that position.

#### X. OTHER RESPONSES TO PREMANUFACTURE GENERIC INFECTION CASES

Three cases show that a court dealing with the Directive or its clones might simply opt to use norms opposite to those chosen by the Hepatitis C court.<sup>160</sup> In

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157. The approach of the court in the Hepatitis C case seems to dictate that the vaccine is defective. *In re Hepatitis C Litig.*, 3 All E.R. at 339. But how odd, then, that such a lifesaving product with no substitutes is defective but a nonlifesaving standard product with many safer substitutes, such as a car, may be judged nondefective!

158. Green Paper on Innovation from the European Comm’n, COM(95)688 final at 19. See Christopher Hodges, *Development Risks: Unanswered Questions*, 61 MOD. L. REV. 560, 561-62 (1998). This was also the concern of ECOSOC when it advised the Directive that it should not inhibit innovation. See *supra* note 32. But see Mark Mildred & Geraint Howells, *Comment on Development Risks: Unanswered Questions*, 61 MOD. L. REV. 570 (1998) (critiquing Hodges’s article).

159. In my view, the text of the Directive clearly failed to achieve the imposition of strict liability on product manufacturers. Unless those who hoped that it would do so accept that it failed to do so and act to ensure that the Directive is reformed carefully and precisely to achieve this imposition, continued confusion is likely as courts are forced “to make it up as they go along.” The Hepatitis C case also raises an interesting issue concerning the feasibility of a contribution action by the National Blood Authority (NBA) against any pharmaceutical company who had supplied the NBA with infected blood products. In some other jurisdictions such companies are required to contribute substantial sums to the state compensation schemes for Hepatitis C victims of infected blood products. Ina Brock, *State Compensation for HCV Infections in the Federal Republic of Germany*, EUROPEAN PROD. LIAB. REV., Dec. 2000, at 16.

160. Certainly it is not unusual for common law courts dealing with strict liabilities to embrace this opposite norm. For example, when addressing the strict liability provision against misleading and deceptive conduct in § 52 of the Trade Practices Act, 1974 (Austl.), a court recently stated that “it cannot reasonably be expected that the supplier is to inform the public of every possible risk . . . in the ordinary course of human affairs things go wrong in connection with the supply of products and services and . . . nobody could reasonably assume, absent disclosure, that such supply will be risk free.”

*Scholten v. The Foundation Sanquin of Blood Supply*,<sup>161</sup> a Dutch court held that while the HIV infected blood was defective, it was protected by the development risk defence in the Directive. Similarly, a Canadian judgment, albeit not a case on the Directive, reflected the same normative impulse as that at work in *Scholten*. In *Ter Neuzen v. Korn*,<sup>162</sup> the Canadian Supreme Court refused to imply a warranty of merchantability in a case involving HIV infection from an artificial insemination procedure, noting in dictum that, "it must be recognized that biological products such as blood and semen, *unlike manufactured products*, carry certain inherent risks."<sup>163</sup> The court held that at most the standard should be one of reasonableness.<sup>164</sup>

Thirdly, we have *Ryan v. Great Lakes Council*, an Australian case of food poisoning from hepatitis-infected oysters.<sup>165</sup> The plaintiffs failed in their claim under a clone of the Directive. Though the judge found the product was defective, he held that the development risk defence protected if the defect in the individual product was not capable of discovery and this was the case with the oysters.<sup>166</sup> In terms of our conflicting norms, the judge agreed with the impulse in *Scholten* and *Ter Neuzen*—that the risk of scientific unavoidability should not rest on the oyster-growers.<sup>167</sup> He refused to distinguish between the unfairness in holding manufacturers liable for *design flaws* they could not discover as in *Thalidomide* and the unfairness in holding them liable for premanufacturing infections that they could not discover.

More fundamentally, the *Ryan* case, like most infection cases, highlights the artificiality of any product/service distinction in our law of obligations and the incoherence of the idea that products liability can sensibly look at the product and not the human behaviour surrounding its production and handling. In *Ryan*, the hepatitis infection of the oysters could have been prevented by reasonable surveillance of the quality of the water supply; thus, although the claim under the clone of the Directive failed, parallel claims in negligence succeeded.<sup>168</sup> This vitality of negligence,<sup>169</sup> a vitality rooted in its focus on human behaviour and the

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Johnson Tiles Pty v. Esso Austl. Ltd. (2000) 104 F.C.R. 564, 592, ¶ 67.

161. *Scholten/The Foundation Sanquin of Blood Supply*, Rb., Amsterdam, 3 februari 1999, NJ 621 (ann. DJV).

162. *Ter Neuzen v. Korn*, [1995] 3 S.C.R. 674.

163. *Id.* at ¶ 108.

164. *Id.*

165. *Ryan v. Great Lakes Council* (1999) 78 F.C.R. 309, *on appeal sub nom.*, *Graham Barclay Oysters Pty v. Ryan* (2000) 102 F.C.R. 307.

166. *Graham Barclay Oysters Pty*, 102 F.C.R. at 462.

167. *Id.*

168. In this regard, it is interesting to note two recent Italian decisions (not dealing with the Directive) in which the Italian Ministry of Health was found to have been careless in relation to the risks of infections in blood, including the risk of Hep C infection during the same years at issue in *In re Hepatitis C Litig.* See Roberto Marengo, *Court of Rome Rules on Liability for HIV, HBV and HCV Infections*, EUROPEAN PROD. LIAB. REV., Sept. 2001, at 28 (discussing Court of Appeal of Rome decision Oct. 2000) and Court of Rome decision (June 2001)).

169. See Gary T. Schwartz, *The Vitality of Negligence and the Ethics of Strict Liability*, 15 GA. L.REV. 963 (1981).

platform it provides in each case for the examination of the complex moral and economic dilemmas that can characterize product cases, prompts one to ask why we have a separate regime for product injuries at all.

But infection cases also prompt us to ask why such a regime is limited to products that have been commercially supplied. It is certainly tough to justify why we have a separate liability rule that only covers cases of infection by contact with infected products that have been commercially supplied, but not cases of say the American hunters infected by deer suffering from CWD, or neighbours infected by the wind from pyres burning stock slaughtered in a foot and mouth epidemic,<sup>170</sup> or farmers, abattoir workers, and slaughtermen infected by diseased animals?<sup>171</sup>

Certainly we now see from the *Restatement Third* that the experiment has been abandoned in the United States in the case of product conditions classed as design or warning conditions. In these cases, the U.S. courts now recognize that you cannot coherently detach the concept of defect from behaviour. Perhaps it will be the infection cases that finally convince jurisdictions on both sides of the Atlantic and beyond that the treatment of imposing true strict liability only for manufacturing defects is not only anomalous and normatively unacceptable, but unworkable. If we are to treat infection cases as harshly as manufacturing error cases, which is what the English court chose to do in the Hepatitis C case, we will have to explain why transfusion recipients get a strict liability remedy while it is refused to those who, for example, collected the blood from infected donors or were otherwise environmentally infected.<sup>172</sup>

## XI. CONCLUSION

When we look through the dramatic lens of premanufacture generic infection product cases, we see that neither the *Restatement Third* nor the Directive coherently cope with the challenges they throw out. These cases force us to confront the question of whether it was wise, either as a matter of theory or pragmatism, for the *Restatement Third* to carve out for "special" treatment classes of product claims according to proof shortcuts and according to product classes such as food. They also prompt us to ask whether it was wise to give separate treatment to manufacturing errors on the one hand from that given to design and warning conditions on the other. Even more fundamentally, the infection cases also

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170. See DAILY EXPRESS (London), May 25, 2001 (discussing atmospheric and water supply risk of CJD infection from burning of cattle in the foot and mouth cull); see also Nigel Hawkes, *Animal Pyres Linked to Cancer Risk in Milk*, TIMES (London), May 26, 2001, at 10 (discussing chemical contamination by this route: More than six million of the animals slaughtered in the 2001 foot and mouth outbreak in the United Kingdom were burned on massive funeral pyres. Yet this process itself increased the atmospheric dioxin level by an average of eighteen percent over the nation, and there is now major concern about the contamination of milk from nearby herds!).

171. See David Brown, *Worst of the Epidemic Over by Election Day*, DAILY TEL. (London), Apr. 26, 2001, at 15; Sally Leany, *We're Not Safe Yet*, DAILY TEL. (London), Apr. 23, 2001.

172. Each year in the United States 5,600 health-care workers acquire Hep C through accidental needle sticks. See K. Elieson, *Legal Standards Applicable to Transmission of HIV and Other Communicable Diseases*, 61 TEX. B.J. 938, 944 (1998).

force us to question why in the *Restatement Third* and the Directive we tolerate a special tort rule for injuries that happened to have been caused by commercially supplied products.

From the perspective of many decades of experience, there does not seem to be any particular moral, economic, or social reason why the victims of such injuries should have been accorded any more special treatment than the victims of medical misadventures or environmental disasters—both areas in which plaintiffs typically find it hard to establish liability under traditional causes of action. The concern I share with other commentators is that the creation of special rules for injuries associated with commercially supplied products warps our laws of obligation for little if any benefit and blinkers us to important common themes that run through all personal injury cases generally.

Though neither the *Restatement Third* nor the Directive provides a clear accommodation for premanufacture generic infected product cases, we have seen that the reasons for their failure differ. Both regimes have developed through the particular, accidental, and necessarily limited local experience.<sup>173</sup> Both have gaps. Both sides have lessons to learn from the experience of the other. The world's legal systems are not in competition. We simply do not confront the same advantages and disadvantages. But there are also limits on the fruitful lessons we can learn from other systems. Comparative law can be illuminating, but it has many limitations, not the least of which are the language barriers and prejudices most of us labour under when seeking to learn from the experience of other systems. It is a valuable corrective to the more ambitious claims of comparative law scholarship to remember that, even among most comparativists, deep expertise is limited to a few systems.

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173. Eric A. Feldman, *Blood Justice: Courts, Conflict, and Compensation in Japan, France, and the United States*, 34 LAW & SOCIETY REV. 651 (2000).



## APPENDIX A

## COMMON LAW SYSTEMS: WHAT DO THEY HAVE IN COMMON?

						Compare Non-Common Law Systems	
Substantive Legal Differences	UK	Canada (Not Quebec)	Australia	New Zealand	USA	<i>EU itself</i>	<i>EU Member States, except Eire &amp; UK</i>
Written Constitution?	No	Yes	Yes	Yes	Yes	No	Yes
Federal system that explicitly divides legislative competence on basis of subject matter?	No	Yes	Yes	No	Yes	No	Yes/No
Sub-national legislative capacity in Private Law?	No	Yes	Yes	No	Yes	N/A	Yes/No
Unitary (i.e. national) Private Common (i.e. judge-made) Law?	Yes	Yes	Yes	Yes	No		
Does fact-finder give written reasons?	Yes	Yes	Yes	Yes	No	Yes	Yes
Level of judicial loyalty to precedent, consistency of outcome?	High	Medium	High	High	Medium	Relatively High	???
Publicly-funded law reform bodies?	Yes	Yes	Yes	Yes	No	No	Yes/No?
<b>Legal System Differences</b>							
Adversarial?	Yes	Yes	Yes	Yes	Yes	Yes	Yes/No?
Are juries common in private law?	No	Varies	No	No	Yes	No	No
Are punitive damages rare in private law?	Yes	Yes	Yes	Yes	No	Yes	Yes
Are contingency fee arrangements often used?	No	Yes	No	No	Yes	No	No
Loser pays winner's costs?	Yes	Yes	Yes	Yes	No	Yes	Yes
Are (many) judges elected?	No	No	No	No	Yes	No	No
Level of influence of the Legal Academy on the development of the common law?	Not High	High	Not High	Not High	Very High	High W.R.T. A-G	High?

2002]

## BUGS IN ANGLO-AMERICAN PRODUCTS LIABILITY

1257

						Compare Non-Common Law Systems	
Substantive Legal Differences	UK	Canada	Australia	New Zealand	USA	<i>EU itself</i>	<i>EU Member States, except Eire &amp; UK</i>
Broad consensus for comprehensive social security/welfare support?	Yes	Yes	Yes	Yes	No	<i>N/A</i>	<i>Yes</i>
Is the quantum of damages subject to tight judicial control?	Yes	Yes	Yes	Yes	No	<i>N/A</i>	<i>Yes</i>

## APPENDIX B

HOW PREMANUFACTURE GENERIC INFECTION (P-M GI) CONDITIONS STRADDLE  
 PRO- AND CON ARGUMENTS CONCERNING STRICT LIABILITY  
 3R = RESTATEMENT THIRD.

<i>Manufacturing error: arguments for strict liability</i>	<i>P-M GI cases: favouring strict Liability</i>	<i>Premanufacture Generic infection cases: characteristics</i>	<i>P-M GI cases: not favouring strict liability</i>	<i>Design conditions: arguments against strict liability</i>
<i>Risk of unavoidable failure of manufacturing system should be on the manufacturer</i>	<u>Hep C</u> 2001	<i>Danger not introduced by manufacturing system... militates against imposition of strict liability</i>	<u>Scholten</u> 1999  <u>Korn</u> 1995  <u>Ryan</u> 1999	<i>Risk of unavoidable inadequacy of scientific knowledge should not be on the manufacturer</i>
<i>Fair to defendant to impose liability for unforeseeable product conditions</i>	<i>Treatment under 3R, of raw materials</i>	<i>Risk is foreseeable in the generic class; but unforeseeable in the individual product. . .</i>	<i>Blood shield statutes</i>  <i>Treatment under 3R, of food seen as "inherently" infected</i>	<i>Unfair to defendant to impose liability for unforeseeable product conditions</i>
<i>The pragmatic convenience of the production-line norm supports imposition of strict liability</i>	<i>Treatment under 3R, of food seen as "adulterated" by infection</i>	<i>The existence of the intended/hoped for production-line norm lends pragmatic support to imposition of strict liability</i>		<i>The absence of a convenient norm militates against imposition of strict liability</i>

APPENDIX C

CASES INVOLVING THE DIRECTIVE AND ITS CLONES<sup>174</sup>

EUROPEAN COURT OF JUSTICE

1. Case C-203/99, *Henning Vedfeld v. Arhus Amtskommune*, 2001 E.C.R. I-3569 (the first products liability Reference for a Preliminary Ruling to be referred to the European Court of Justice concerning Council Directive 85/374/, 1985 O.J. (L 210) 29). *See also* L.Mattheussens & B.Oosting, *The Danish Kidney Case*, EUROPEAN PROD. LIAB. REV., June 2001, at 20.
2. Case C-300/95, *European Comm'n v. United Kingdom*, 1997 E.C.R. I-2649, [1997] All E.R. 481.
3. Case C-293/91, *European Comm'n v. France*, 1993 E.C.R. I-1.

UNITED KINGDOM

1. *Bogle v. McDonald's Rests. Ltd.*, [2002] E.W.H.C. 490 (Q.B.) (Field, J.) (concerning personal injuries from hot drinks)
2. *Smithkline Beecham Plc. v. Horne-Roberts*, 2001 E.W.C.A. 2006 (Civ. 2001) (dismissing appeal from *Horne-Roberts v. Merck & Co.*, 2001 C.P. Rep. 80 (Q.B. 2001) (Bell, J.)).
3. *In re Hepatitis C Litig., A v. Nat'l Blood Auth.*, 3 All E.R. 289 (Q.B. 2001) (Burton, J.) (alleging defective blood resulting in hepatitis C infections; on Oct. 28, 1999, trial judge had refused application for a Reference to the European Court of Justice for a Preliminary Ruling concerning Council Directive 85/374/EEC, 1985 O.J. (L 210) 29); *See also* Simon Pearl, *Damaging Goods*, SOLICITORS J., May 11, 2001, at 424.
4. *Abouzaid v. Mothercare Ltd.*, No. B3/2000/2273, 2000 WL 1918530 (Eng. C.A. Dec. 21, 2000) (alleging defective fleece-lined "Cosytoes" infant sleeping bags).
5. *Worsley v. Tambrands Ltd.*, 2000 P.I.Q.R. P95 (Q.B. 1999) (Ebsworth, J.) (alleging defective tampons).
6. *Foster v. Biosil*, 59 B.M.L.R. 178 (Q.B. 2000) (Cherie Booth, QC) (alleging defective breast implants).

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174. Those readily available in English or English translation.

7. Richardson v. LRC Prods. Ltd., 2000 Lloyd's Rep.(Medical) 280 (Q.B.) (Kennedy, J.) (alleging a defective condom).

8. Relph v. Yamaha Motor Co., (Q.B. 1996) (Brown, J.) (unreported decision) (alleging defective all-terrain vehicle). See Simon Pearl, Note, 18 PROD. LIAB. INT'L 121 (1996) (discussing Relph v. Yamaha Motor Co.).

9. A.B. v. S.W. Water Servs. Ltd., 1993 Q.B. 507 (Eng. C.A. 1992) (involving a group claim arising from chemically contaminated drinking water).

#### NETHERLANDS

1. Schloten/The Foundation Sanquin of Blood Supply, Rb., Amsterdam, 3 februari 1999, NJ 621 (ann. DJV) (concerning HIV infection from blood transfusions) (also known as Hartman v. Stichting Sanquin Bloedvoorziening; A v. OLVG Hosp. Amsterdam).

#### ITALY

1. Daniele Bonaca & Roberto Marengo, *An Overview of Product Liability Law in Italy*, 5 EUROPEAN PROD. LIAB. REV., Dec. 2001, at 5 (noting three decisions: Court of Rome (Mar. 17, 1998); Supreme Court (Sept. 29, 1995); Court of Monza (July 20, 1993)).

#### AUSTRIA, BELGIUM, GREECE, PORTUGAL, & SPAIN

1. J. Peris, *Liability for Defective Products in the European Union: Developments Since 1995—The European Commission's Green Paper*, CONSUMER L.J., 1999, at 331 (describing a series of cases); Antonio J. Vela Sánchez, *Products Liability in Spain*, 32 TEX. TECH. L.REV. 979 (2001) (focusing on Spain).

#### GERMANY

1. BGHZ 129, 353; VIZR 158/94, IN NJW 1995, 2162. See also Christopher Hodges, *The Case of the Exploding Bottle of Water*, 18 PROD. LIAB. INT'L 73 (1996).

#### FRANCE

1. T.G.I. Provence, Oct. 2, 2001, D. [2001], 1R.3092 (concerning a fireplace glass window that exploded). See also C.Larroumet, *The Exploding Fireplace Case*, EUROPEAN PROD. LIAB. REV., Dec. 2001, at 30.

2. CA Toulouse, Feb. 22, 2000, Gaz. Pal. [2001], 2, somm., 11 (concerning contraction of trichinellosis from eating defective horsemeat). See also

2002]                    BUGS IN ANGLO-AMERICAN PRODUCTS LIABILITY                    1261

C.Larroumet, *Toulouse Court of Appeal Rules on Suppliers' Liability*, EUROPEAN PROD. LIAB. REV., Mar. 2001, at 22.

AUSTRALIA

1. Cheong v. Wong & Ors (2001) N.S.W.S. Ct. R. 881 (alleging defective tire).
2. Carey-Hazell v. Getz Bros. & Co. Pty (2001) F.C.A. 703 (alleging defective prosthetic heart valve).
3. Cook v. Pasminco Ltd (2000) 99 F.C.R. 548 (concerning environmental injury); *See also* Cook v. Pasminco Ltd [No 2] (2000) 107 F.C.R. 44.
4. Ryan v. Great Lakes Council (1999) 78 F.C.R. 309, *on appeal sub nom.*, Graham Barclay Oysters Pty v. Ryan (2000) 102 F.C.R. 307 (alleging defective oysters).
5. Lopez v. Star World Enter. Pty (1999) F.C.A. 104, BC9900314 (alleging defective food).
6. Australian Competition & Consumer Comm'n v. Glendale Chem. Prods. Pty (1998) 40 I.P.R. 619, *aff'd by*, (1999) 90 F.C.R. 40 (concerning defective chemical drain cleaner).

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