

COMMENT

PRODUCT LIABILITY BARRIERS TO THE COMMERCIALIZATION OF BIOTECHNOLOGY: IMPROVING THE COMPETITIVENESS OF THE U.S. BIOTECHNOLOGY INDUSTRY

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I. INTRODUCTION

During the next decade, the biotechnology¹ industry will assume increasing international significance. It offers vast social and economic potential to nations which grant their high-technology sectors freedom to

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1. Biotechnology has been defined as the "intentional manipulation of living organisms, through a research-based program, in order to achieve a useful end product." James T. O'Reilly, *Biotechnology Meets Products Liability: Problems Beyond the State of the Art*, 24 HOUS. L. REV. 451, 452 n.2 (1987) (citing IVER COOPER, *BIOTECHNOLOGY AND THE LAW* (1985)); see also Jeffrey N. Gibbs & Jonathan S. Kahan, *Federal Regulation of Food and Food Additive Biotechnology*, 38 ADMIN. L. REV. 1 (1986); Edward L. Korwek, *FDA Regulation of Biotechnology as a New Method of Manufacture*, 37 FOOD DRUG COSM. L.J. 289, 291 (1982).

compete in world markets.² Genetically improved food materials, purer vaccines, or simpler and more accurate diagnostic products, for example, may provide social benefits unavailable using conventional production techniques but within the reach of biotechnology.³ Economic rewards will likely accrue to nations leading development in this crucial field if, as expected, biotechnology products can be manufactured more cheaply, with greater purity, in larger quantities, and with less pollution and energy consumption than their conventional counterparts.⁴

The United States officially recognizes the importance of biotechnology and supports its development.⁵ Despite official posture and though the United States has played a leading role in biotechnological innovation and development, its competitive advantage in high technology innovation and commercialization over its

2. "As commercial biotechnology enters the 1990's, there are uncertainties, of course—but there are also many certainties. It is certain that biotechnology is fundamental. The exploration and manipulation of life structures and processes at the molecular level, and the application of the knowledge gained, represents a genuine revolution for society at large, a revolution just beginning to unfold . . . the new biotechnology creates a vastly greater range of possibility and a very different pace. This industry is necessary and permanent A second certainty is that an array of powerfully innovative products will be introduced in the early 1990's by the larger segments of industry—therapeutics, diagnostics, agriculture, instrumentation—and perhaps by smaller segments such as bioremediation. The wave of technology development in the 1970's and 80's will be followed by a wave of product introductions in the '90's." G. STEVEN BURRILL WITH THE ERNST & YOUNG HIGH TECHNOLOGY GROUP, *BIOTECH 90: INTO THE NEXT DECADE*, at i (1989). [hereinafter *BIOTECH 90*].

3. OFFICE OF TECHNOLOGY ASSESSMENT, U.S. CONGRESS, *COMMERCIAL BIOTECHNOLOGY: AN INTERNATIONAL ANALYSIS* 6-7 (1984).

The potential benefits of this new technology are immense. Scientists can introduce genes from human or other animal cells into bacteria to obtain the production, on a commercial scale, of products coded by the human or animal genes. For example, recombinant DNA could very well be the future of the pharmaceutical industry. Using recombinant techniques, researchers are developing therapeutic drugs such as human insulin, growth hormone and interferon. Scientists are using the technology to develop improved processes in making antibiotics. This technique holds great promise for cures for tay-sacks [sic] and sickle cell anemia along with vaccines for influenza and hepatitis.

Genetic engineering techniques are not limited in their application to medicine. The U.S. Department of Scientific and Industrial Research is currently working on a genetically engineered microorganism for the fixation of nitrogen, essential in agriculture, which will lead to a direct reduction in dependence on fertilizer. Genetic recombinations also have wide applications in the chemical and energy industries. For example, researchers have created ethylene oxide and yeast bacteria, which may enable producers of gasohol to eliminate the distillation process. The list of possible applications goes on. In years to come scientists and industry analysts expect the market to be flooded with everything from bioengineered microorganisms that can mine copper and gobble up oil spills to a specialized cancer therapy that will deliver treatment only to the affected cells. Scientists may be able to develop organisms to assist in the disposal of industrial waste and to degrade metals and other materials.

Walter L. Williams, Jr., *Transnational Aspects of Biotechnology*, 19 *LAW/TECHNOLOGY* 3, 9-10 (1986) (citations omitted).

4. INT'L TRADE ADMIN., U.S. DEP'T OF COMMERCE, *HIGH TECHNOLOGY INDUSTRIES: PROFILES AND OUTLOOKS—BIOTECHNOLOGY* 47 (1984) [hereinafter *PROFILES*].

5. Coordinated Framework for Regulation of Biotechnology, 51 *Fed. Reg.* 23,302 (1986).

international trading partners has eroded in recent years.⁶ Product liability law in the United States has played a major role in this erosion and represents a particularly severe barrier to innovation and commercial growth within the biotechnology industry.⁷ Product liability law plays a large role in determining the extent to which U.S. biotechnology firms successfully commercialize biotechnology.

Although various statutory and administrative barriers to the commercialization of biotechnology products pervade the U.S. biotechnology industry,⁸ this comment argues that product liability law poses a grave risk to our biotechnology industry. U.S. product liability law bars entry into product markets and affects domestic biotechnology firms more harshly than firms in other industries.⁹ As a result, socially valuable products never reach the market. Therefore, on balance, policy underlying the general application of product liability is inconsistent with its application to the biotechnology industry. The law should be modified. This comment recommends changes designed to make the product liability system more favorable to U.S. biotechnology firms, without ignoring the needs of injured consumers.

II. THE U.S. STRICT PRODUCT LIABILITY SYSTEM

Before showing how the U.S. system impedes firms, it is necessary to understand the history and content of U.S. product liability law. The following section reviews current U.S. product liability law as it relates to biotechnology and shows that the law applies severely to biotechnology products and firms.

6. Joel Dreyfuss, *Getting High Tech Back on Track*, FORTUNE, Jan. 1, 1990, at 76.

7. PROFILES, *supra* note 4, at 71.

8. *Id.* at 70. The U.S. Department of Commerce recognizes the concerns of the biotechnology industry with regard to such regulatory barriers. For example, the Food and Drug Administration's ("FDA") regulatory process for approval of a new pharmaceutical drug includes: (1) the discovery phase; (2) the preclinical phase; (3) the phase of demonstration of clinical safety and efficacy; (4) the new drug application (NDA); and (5) the marketing phase. The entire process is estimated to cost \$74 million on average and take 7 to 10 years to complete. *Id.* at 70. The Department of Commerce has additionally documented that the extensive regulatory process in the United States has forced firms to carry out the development of new pharmaceutical products in countries where the approval processes are less stringent. According to one study, U.S. firms spent more than \$220 million in research and development funds overseas in 1978. *Id.* at 71.

9. U.S. product liability law refers to the body of statutory, administrative and case law from which manufacturer liability is derived for defective design, manufacture or warning relating to marketed products. *See, e.g.,* Greenman v. Yuba Power Prods., 377 P.2d 897 (Cal. 1962); Escola v. Coca-Cola Bottling Co., 150 P.2d 436 (Cal. 1944); Brown v. Superior Court, 751 P.2d 470 (Cal. 1988), *cert. denied*, 485 U.S. 942 (1988); Hurley v. Lederle Lab., 851 F.2d 1536 (5th Cir. 1988) (failure to warn); Petty v. United States, 740 F.2d 1428 (8th Cir. 1984) (failure to warn); Reyes v. Wyeth Lab., 498 F.2d 1264 (5th Cir. 1974), *cert. denied*, 419 U.S. 1096 (1974); Feldman v. Lederle Lab., 460 A.2d 203 (N.J. Super. Ct. App. Div. 1983), *rev'd on other grounds*, 479 A.2d 374 (N.J. 1984) (failure to warn).

A. Switch from Negligence to Strict Product Liability

The concept of strict liability assumed centrality in U.S. product liability law during the early 1960's, when it replaced negligence as the predominant theory of recovery for product related injuries. Under the negligence standard, companies were obligated to exercise reasonable care in designing and manufacturing products and in providing product warnings. The shift to strict liability has changed the focus of courts and juries from concern with the care utilized by manufacturers to an examination of whether products themselves are defective. The focus now centers on the quality of product manufacture and design, and the adequacy of the manufacturer's warnings.¹⁰

Justice Roger Traynor's landmark decision in *Greenman v. Yuba Power Products*¹¹ first recognized the application of the strict liability standard in the area of tort law:

Strict liability has usually been based on the theory of an express or implied warranty running from the manufacturer to the plaintiff, [i] the abandonment of the requirement of a contract between them, [ii] the recognition that the liability is not assumed by agreement but imposed by law, [iii] and the refusal to permit the manufacturer to define the scope of its own responsibility for defective products make clear that the liability is not one governed by the law of contract warranties but by the law of strict liability in tort.¹²

Plaintiffs must show that a defect in product design or manufacture unknown to them rendered the product unreasonably dangerous and caused injury.¹³

B. Elements of Strict Product Liability

Nearly all states have adopted a theory of strict product liability based on the Restatement (Second) of Torts, section 402A ("Section 402A").¹⁴ However, product liability's doctrinal particularities depend

10. See, *infra*, notes 11-13 and accompanying text.

11. 377 P.2d 897 (Cal. 1963); see also *Escola v. Coca-Cola Bottling Co.*, 150 P.2d 436, 440-41 (Cal. 1944).

12. *Greenman*, 377 P.2d at 901.

However intermittently such injuries may occur and however haphazardly they may strike, the risk of their occurrence is a constant risk and a general one. Against such a risk there should be general and constant protection and the manufacturer is best situated to afford such protection. *Escola*, 150 P.2d at 441 (Traynor, J., concurring) (justifying the strict theory of products liability).

13. *Greenman*, 377 P.2d at 901. The elements of product liability under commonly accepted U.S. tort law remain: (1) the existence of a defect, (2) causation of injury to the user, and (3) the presence of the defect at the time the product left the control of the manufacturer. Stephan J. Leacock, *A General Conspectus of American Law on Product Liability*, J. BUS. L., May 1991, at 273, 276 n.21.

14. RESTATEMENT (SECOND) OF TORTS § 402A (1965).

Section 402A. Special Liability of Seller of Product for Physical Harm to User or Consumer.

upon state common law. Much of the uncertainty surrounding product liability suits stems from inconsistency between state product liability laws.

Despite inconsistency, courts agree that in order for strict liability to apply under Section 402A, products must be "in a defective condition unreasonably dangerous to the user or consumer."¹⁵ State courts tend to define "defective" broadly and flexibly, thus enhancing the protection afforded product users.¹⁶ They view a defective product as one that is flawed in either manufacture, design or in the sufficiency of the warnings given as to its use.¹⁷ In determining whether liability attaches to a defective product, state courts apply one of two distinct tests: (1) a risk-utility test,¹⁸ or (2) a consumer expectations test.¹⁹

The risk-utility analysis attempts to balance society's interests in the product and the protection of consumers by requiring reasonable safety in product design. This analysis forces inquiry into whether the risk of injury outweighs the social utility of the product in question. Where risk exceeds utility, a product is deemed "unreasonably dangerous." Such analysis recognizes a "valid" social interest in product innovation and competitiveness in biotechnology manufacturing industries.²⁰

Under the consumer expectations test, the critical issue is the degree of safety that the reasonable consumer should expect when using the particular product in the manner intended by the manufacturer. The

(1) One who sells any product in a defective condition unreasonably dangerous to the user or consumer or to his property is subject to liability for physical harm thereby caused to the ultimate user or consumer, or to his property, if

(a) the seller is engaged in the business of selling such product, and

(b) it is expected to and does reach the user or consumer without substantial change in the condition in which it is sold.

(2) The rule stated in Subsection (1) applies although

(a) the seller has exercised all possible care in the preparation and sale of his product, and

(b) the user or consumer has not bought the product from or entered into any contractual relation with the seller.

Section 402A has been adopted by all states except Michigan, North Carolina, Virginia, Wyoming, and West Virginia. Leacock, *supra* note 13, at 273 n.2. Of course, negligence is also a basis for manufacturer's liability and it is often used as an alternative basis for products liability. See, e.g., McNeal v. Hi-lo Powered Scaffolding, Inc., 836 F.2d 637, 638 (D.C. Cir. 1988); Toner v. Lederle Labs., 828 F.2d 510 (9th Cir. 1987), *cert. denied*, 485 U.S. 942 (1988).

15. RESTATEMENT (SECOND) OF TORTS § 402A (1965).

16. "[T]he consumer of . . . products is entitled to the maximum of protection at the hands of someone, and the proper persons to afford it are those who market the products." RESTATEMENT (SECOND) OF TORTS § 402A cmt. c (1965). See also Ransome v. Wisconsin Elec. Power Co., 275 N.W.2d 641 (Wis. 1979).

17. See Page Keeton, *Product Liability and the Meaning of Defect*, 5 ST. MARY'S L.J. 30, 33-34 (1973); John W. Wade, *On Product "Design Defects" and Their Actionability*, 33 VAND. L. REV. 551, 551 (1980).

18. See Suter v. San Angelo Foundry & Mach. Co., 406 A.2d 140, 151 (1979).

19. See Ransome, 275 N.W.2d at 648.

20. Leacock, *supra* note 13, at 275.

consumer expectations test utilizes an objective standard and represents a concern for the expectations of the reasonably prudent consumer in the context and circumstances of the use of the particular product.

The imposition of liability by the courts can occur under either the risk-utility or consumer expectation analyses²¹ irrespective of proof that the manufacturer used reasonable care in the design, manufacture or sale of the product in question.²²

The shift of focus away from manufacturer conduct to product condition, embodied in the change from a negligence standard to strict liability standard, makes it easier for plaintiffs to sue manufacturers successfully.²³ This shift in focus should concern biotechnology manufacturers, who are made highly susceptible to the uncertainties of litigation and its related costs. This increased vulnerability to litigation costs is relatively unmitigated due to the erosion of previously effective defenses to strict liability which has accompanied the rise of this doctrine in U.S. courts.

C. The Erosion of the "State of the Art" Defense to Strict Liability

The U.S. system of product liability provides few defenses for manufacturers.²⁴ The most viable of those defenses—the state of the art defense, which "requires a demonstration that the technology available for the manufacture of a safer finished product with [the] same characteristics was not feasible"²⁵—is particularly difficult to establish in cases involving biotechnology. This is true for three reasons.

First, judicial decisions narrowly interpret the "state of the art" defense.²⁶ In *Sturm, Ruger & Co. v. Day*, an Alaska court held that "state-

21. *Id.* In the American tort system, the judge decides the question of which test should be applied. The jury, however, weighs the risks and decides whether the marketing was acceptable in terms of risks and benefits or consumer expectations.

22. *Kerns v. Engelke*, 369 N.E.2d 1284, 1289 (Ill. App. Ct. 1977), *aff'd in part, rev'd in part*, 390 N.E.2d 859 (Ill. 1979). *See also Williams v. Detroit Edison Co.*, 234 N.W.2d 702, 707 (Mich. Ct. App. 1975).

23. Peter Huber, *The Force of Technology*, FORBES, July 13, 1987, at 56, 64 [hereinafter *Force of Technology*].

24. These include contributory negligence, assumption of the risk, consumer product misuse, and the "state of the art" defense. George L. Priest, *The Current Insurance Crisis and Modern Tort Law*, 96 YALE L.J. 1521, 1535-36 (1987); Gary C. Robb, *A Practical Approach to Use of State of the Art Evidence in Strict Products Liability Cases*, 77 NW. U. L. REV. 1 (1977).

25. O'Reilly, *supra* note 1, at 459. *See also* 1 LOUIS FRUMER & MELVIN FRIEDMAN, PRODUCTS LIABILITY § 2.26(8)(a) (The majority of U.S. courts measure liability against the state of the art at the time of marketing of the drug or diagnostic product in question.) *See Olson v. Artic Enter.*, 349 F. Supp. 761, 765 (D.N.D. 1972).

26. Principal weakening of the "state of the art" defense has come at the state court level through restrictions on manufacturers' ability to rebut the defectiveness of a product. *See, e.g., Sturm, Ruger & Co. v. Day*, 594 P.2d 38, 43-44 (Alaska 1979), *modified*, 615 P.2d 621 (Alaska 1980), *cert. denied*, 454 U.S. 894 (1980); *Cunningham v. MacNeal Memorial Hosp.*,

of-the-art" refers to customary, industry practice.²⁷ As a result, the *Sturm* court found that "[i]n cases predicated upon strict liability, evidence of industry standards has even less probative value [than in negligence actions]."²⁸ Thus the *Sturm* court disallowed use of the state-of-the-art defense.²⁹ In *Cunningham v. MacNeal Memorial Hospital*, the Illinois Supreme Court rejected the argument that blood products then in use complied with the state-of-the-art in terms of safety from hepatitis contamination. The Court stated that "[t]o allow a defense to strict liability on the ground that there is no way, either practical or theoretical, for a defendant to ascertain the existence of impurities ... would emasculate the doctrine ... and signal a return to a negligence theory."³⁰ In *O'Brien v. Muskin Corp.*, the New Jersey Supreme Court, while recognizing the value of evidence as to the state-of-the-art in determining product defect and in applying a risk-utility analysis, held that the defense is not absolute.³¹ Further, in *Beshada v. Johns Manville*, the New Jersey Supreme Court expressly disallowed the state-of-the-art defense to the issue of failure to warn.³²

Second, courts and juries rejecting the "state-of-the-art" defense have done so partly due to so-called "technology-phobia," the fear of unascertainable harm resulting from new technologies beyond common knowledge.³³ Effective use of experts can diminish the effects of "technology-phobia"³⁴ by increasing jurors' understanding of biotechnology. However,

266 N.E.2d 897, 902-04 (Ill. 1970); *O'Brien v. Muskin Corp.*, 463 A.2d 298, 306 (N.J. 1983); *Beshada v. Johns-Manville Prods. Corp.*, 447 A.2d 539, 548 (N.J. 1982).

27. *Sturm*, 594 P.2d at 44.

28. *Id.* at 45.

29. *Id.* (allowing evidence of the state-of-the-art as one factor in determining product defectiveness). See also *Gelsumino v. E.W. Bliss Co.*, 295 N.E.2d 110, 113 (Ill. App. Ct. 1973); *Olson v. A. W. Chesterton Co.*, 256 N.W.2d 530, 540 (N.D. 1977); *Collins v. Ridge Tool Co.*, 520 F.2d 591 (7th Cir. 1975); Jerry J. Phillips, *The Standard for Determining Defectiveness in Products Liability*, 46 U. CIN. L. REV. 101, 115 (1977); Sidmey Z. Karasik, *State of the Art or Science, Is it a Defense to Products Liability?*, 60 ILL. B.J. 348 (1972); Robert Traynor, *The Ways and Meanings of Defective Products and Strict Liability*, 32 TENN. L. REV. 363, 367, 370 (1965).

30. *Cunningham*, 266 N.E.2d at 902.

31. *O'Brien*, 463 A.2d at 305.

32. *Beshada*, 447 A.2d at 546.

33. O'Reilly, *supra* note 1, at 477. See also Peter Huber, *Safety and the Second Best: The Hazards of Public Risk Management in the Courts*, 85 COLUM. L. REV. 277, 281 (1985) [hereinafter *Safety and the Second Best*] (indicating that the layperson's aversion to public risks is shared by research in and industrial use of recombinant DNA as perhaps the most significant public risk-creating technology). Barry R. Furrow, *Governing Science: Public Risks and Private Remedies*, 131 U. PA. L. REV. 1403, 1404-06 (1983). See also Milton Katz, *The Function of Tort Liability in Technology Assessment*, 38 U. CIN. L. REV. 587, 588-91 (1969).

34. See Michael Traynor & Brian C. Cunningham, *Emerging Product Liability Issues in Biotechnology*, 3 HIGH TECH. L.J. 149 (1988); O'Reilly, *supra* note 1 at 477-78. One commentator has noted:

[j]urors ... are not experts on technology or its risks. When jurors are asked to categorize technologies (as distinct from their inventors or managers) as good, bad or ugly, the answers follow a predictable pattern. Age, familiarity and ubiquity are the most potent legitimizing forces known to the modern liability system. The inexperienced juror is predisposed to spot "defects" in technologies that are unfamiliar or adventuresome.³⁵

The disposition of lay juries against technology highlights an inherent irony in U.S. product liability law.³⁶ Lay juries and judges without high technology expertise, rather than expert regulators who understand the risks and benefits of biotechnological innovation, have the final decision-making capacity in terms of product liability.³⁷

A third reason for difficulty exists even where jurors understand the technology. Evidence suggests that, while standards of care are well settled in many industries,

[q]uite the opposite will appear true in connection with new and innovative technologies. A new technology whose use culminates in a specific, identifiable harm will almost always appear to the courts to be a technology that should and easily could have been avoided. Tort liability is thus likely to replicate the bias against new technology that so typifies prospective risk regulation in the courts.³⁸

Without a settled standard of care, even where the FDA approves products,³⁹ lay juries may treat biotechnology products more harshly than conventional products for purposes of tort liability.

As a result of these three factors, the judicial environment is at-odds with the biotechnology industry in the sense that it is relatively reluctant to allow the "state of the art" defense in cases involving high technology-based products. The comparative unavailability of the "state of the art"

Our nation's bloated tort system is tough on small businesses . . . which can't afford costly lawsuits. What's even worse, the system, in conjunction with the bureaucracy, is beginning to strangle development and marketing of new technology. This could well be the greatest of all dangers to American competitiveness and to our standard of living . . . Old technologies bear regulatory and judicial burdens, too, but the newer ones are handicapped. That's because the old is innocent until proven guilty, while the new is guilty until proven innocent. The difference is important when the trial—whether in superior court or at the FDA—costs millions of dollars . . . We—the very society that always wanted the latest—have developed a bias against the new.

Force of Technology, *supra* note 23, at 56.

35. *Force of Technology*, *supra* note 23, at 64.

36. What is acceptable proof of safety under FDA law may be proof of an unreasonably dangerous product under the tort law. The solution may be legislation which recognizes the equality of tort law's risk-utility equation and the regulatory findings of acceptable risk and which therefore makes the FDA decision presumptively acceptable as an exception from liability. O'Reilly, *supra* note 1, at 483 (specifying that FDA approval documentation can actually be used as a basis for finding liability in court).

37. *Force of Technology*, *supra* note 23, at 64.

38. *Safety and the Second Best*, *supra* note 33, at 319 n.147.

39. Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. 23,302, at 23,310 (1986).

defense makes biotechnology manufacturers more vulnerable than conventional manufacturers of similar products in product liability suits. Effective defenses like the "state of the art" defense simply do not apply as they do for conventionally prepared products. As a result, biotechnology manufacturers face liability which is more absolute than strict in character.

D. The "Unavoidably Unsafe Product" Defense

One way to circumvent effects of the erosion of the state of the art defense would be to apply the "unavoidably unsafe product" exception to strict liability, found in comment k to Section 402A of the Restatement (Second) of Torts, to biotechnology products.⁴⁰ Under comment k, a product found to be unavoidably unsafe in design but "properly prepared" escapes strict liability.⁴¹ Comment k recognizes that some products serve a useful social purpose which justifies their marketing regardless of the harm attending their use.

Application of the unavoidably unsafe products exception to biotechnology products would preclude imposition of product liability absent a showing of manufacturer negligence.⁴² With few biotechnology products currently approved for consumer use, it is not yet clear whether courts will give biotechnology products the protection conferred by this exception. Furthermore, the exception has been narrowly construed and currently applies only to products needed to control diseases or to meet other urgent social needs.⁴³ Many biotechnological products will probably not be labelled "unavoidably unsafe" because they have safer, though less efficacious,⁴⁴ conventional counterparts. The potentially harmful effects of these biotechnology products would therefore, fail to meet the comment k standard as this harm could be labelled "avoidable." Finally, the "unavoidably unsafe" categorization may be challenged where the benefits resulting from choosing an innovative method of

40. RESTATEMENT (SECOND) OF TORTS § 402A cmt. k (1965).

41. *Id.* (If a product is properly prepared and accompanied by adequate directions for use and warnings as to potential harm resulting from use, then the product is excepted from the definition of "unreasonably dangerous" under 402A. A sufficient level of purity under FDA standards would arguably satisfy the "properly prepared" standard. *Id.*)

42. Application of the unavoidably unsafe product exception does not preclude claims against manufacturers based on a negligence theory. See, e.g., *Toner v. Lederle Lab.*, 828 F.2d 510 (9th Cir. 1987), *cert. denied*, 485 U.S. 942 (1988).

43. RESTATEMENT (SECOND) OF TORTS § 402A cmt. k (1965). Comment k specifically mentions the rabies vaccine as an example of an unavoidably unsafe product which, though unavoidably dangerous, is justifiably marketed and used. *Id.*

44. Traynor & Cunningham, *supra* note 34, at 160-62 (citing Richard A. Lerner, *Synthetic Vaccines*, SCI. AM., Feb. 1983, at 66); JAMES D. WATSON, JOHN TOOZE & DAVID T. KURTZ, *RECOMBINANT DNA—A SHORT COURSE* (1983).

manufacture in lieu of a conventional method do not outweigh the risk of injury to the public.⁴⁵

E. Policy Behind Strict Liability

Courts, in developing the strict product liability doctrine, recognized the potentially harsh results of passing injury costs on to manufacturers.⁴⁶ They rationalized however that manufacturers would pass such costs on to consumers of their products, effectively spreading the costs over the consuming public. The courts reasoned that strict product liability (1) creates incentives for manufacturers to produce safe products; and (2) induces manufacturers to provide a form of "social insurance."⁴⁷ Manufacturers are harmed to the extent that they cannot pass the costs of insuring on to the consumers in the form of increased prices. Despite judicial rationale, I shall argue that neither of these two policy goals are accomplished when strict product liability is applied to biotechnology products. Rather, strict liability creates an environment in which the imposition of manufacturer-based "social insurance" places a uniquely stifling burden on most biotechnology firms.

III. PRODUCT LIABILITY'S EXCESSIVE COSTS AS A BARRIER TO ENTRY

A. Direct and Indirect Costs

Strict product liability imposes significant direct and indirect operating costs on biotechnology companies.⁴⁸ Direct costs are those costs which are closely related to a company's expenditures for product-related litigation, the payment of claims or awards, and product-specific insurance premiums. Indirect costs include general and administrative expenses associated with compliance with product liability-related duties (e.g., costs associated with discovery in litigation).⁴⁹

45. Debra E. Dahl, Comment, *Strict Product Liability for Injuries Caused by Recombinant DNA Bacteria*, 22 SANTA CLARA L. REV. 117, 145-46 (1982).

46. *Brown v. Superior Court*, 751 P.2d 470 (Cal. 1988).

47. Alan Schwartz, *Proposals for Products Liability Reform: A Theoretical Synthesis*, 97 YALE L.J. 353, 368 (1988) [hereinafter *Products Liability Reform*].

48. See Philip M. Boffey, *Vaccine Liability Threatens Supplies*, N.Y. TIMES, June 26, 1984, at C1.

49. E. Patrick McGuire, *The Impact of Product Liability*, in CONFERENCE BOARD RESEARCH REPORT NO. 908, 17-20 (1988). Merrell-Dow Pharmaceutical produced a drug, Bendectin, which was alleged to be the cause of birth defects in children born to women using the drug. The company has been sued many times and has won each suit except four which are currently on appeal. Bendectin sales were discontinued due to the exorbitant cost of defending against product liability claims. Merrell-Dow claims to have spent \$18 million defending Bendectin though the product produced just \$20 million in revenues per year. The company maintains that more than 12,000 doctors protested the discontinuation of

In addition, litigation burdens company officers with additional responsibilities.⁵⁰ Significant delays result when time best devoted to product development is spent avoiding litigation.⁵¹ Both direct and indirect costs of product liability hurt biotechnology producers disproportionately because, as shown below, biotechnology firms are less able to defray these costs than are conventional manufacturers.

One of the foremost obstacles faced by firms attempting to market biotechnological products is the cost of insuring their products against product liability claims. Product liability insurance costs in the United States have risen dramatically to keep up with increased legal claims.⁵² From 1980 to 1988, the number of product liability suits had increased by 813%.⁵³ From 1974 to 1986, the average jury verdict in product liability cases had increased from \$400,000 to over \$1.8 million.⁵⁴

Dramatically increased premiums for product liability insurance are forcing some manufacturers out of business.⁵⁵ These costs significantly attenuate the viability and competitiveness of smaller and more financially fragile U.S. biotechnology companies.⁵⁶ Eighteen percent of all biotechnology companies rate the cost of product liability insurance as the most important problem facing their firms.⁵⁷ This figure will likely

Bendectin sales because of its usefulness. *Merrell-Dow senior management was repeatedly asked to testify in Bendectin cases. Id.* at 3.

50. *Id.* at 3.

51. *Id.* at 10 (citing the testimony of John B. Curcio, CEO of Mack Trucks Inc., delivered to the House Education and Labor Subcommittee on Commerce, Consumer Protection and Competitiveness, May 5, 1987).

52. INTERAGENCY TASK FORCE ON PRODUCT LIABILITY, U.S. DEP'T. OF COMMERCE, FINAL REPORT (1978); "In 1984 alone, \$9.8 million of manufacturers' litigation costs were not reimbursed by insurance, and by that time, plaintiffs had requested over \$3.5 billion in damages." Evan L. Rosenfeld, *The Strict Products Liability Crisis and Beyond: Is There Hope for an Aids Vaccine?*, 313 JURIMETRICS J. 187, 196 (1991).

53. Mary Beth Neraas, Comment, *The National Childhood Vaccine Injury Act of 1986: A Solution to the Vaccine Liability Crisis?*, 63 WASH. L. REV. 149, 151 (1988) (citing rise in suits from 24 to 150 in 1985).

54. *Id.*

55. Anita Johnson, *Products Liability "Reform": A Hazard to Consumers*, 56 N.C. L. REV. 677, 678 (1978).

56. Victor E. Schwartz, *Proposed Remedies for the American Problem: U.S. Governmental Activity*, 29 MERCER L. REV. 437, 440 (1978) [hereinafter *Proposed Remedies*] (indicating that the problem of the increased cost of products liability insurance is more severe for smaller firms). Products liability costs to industry (liability insurance and litigation costs) are recognized as one significant reason for the withdrawal of manufacturers from vaccine development. PROFILES, *supra* note 4, at 71 (citing HIGH TECH, Apr. 1983, at 64 and N.Y. TIMES, June 26, 1984, at C1).

57. G. STEVEN BURRILL & KENNETH B. LEE, BIOTECH 91: A CHANGING ENVIRONMENT 21 (1990) [hereinafter BIOTECH 91]. By company size, 4% of the large firms, 16% of mid-size firms and 20% of small firms rated product liability insurance costs as their most important concern. *Id.* By market segment, 17% of suppliers, 9% of ag-bio firms, 19% of therapeutic drug manufacturers and 22% of diagnostic manufacturers rate insurance costs as their most significant concern. *Id.* at 22.

rise to 25% during the next five years.⁵⁸ Companies are holding back product introductions, restricting the use of certain products, or even withdrawing from markets in order to avoid costs imposed by the U.S. product liability system.⁵⁹

The current product liability system in the United States restricts the ability of our biotechnology companies to compete internationally due to the added costs and misallocation of resources to which it leads. Surveys show one-half of responding chief executives believe that the product liability system significantly impacts the ability of U.S. firms, in general, to compete in world markets.⁶⁰

Foreign advantages in the development and sale of biotechnology in world markets derive, in part, from the relatively lower costs imposed on foreign producers by their respective product liability systems. Most significant among the disparities are the substantially lower insurance costs facing foreign manufacturers.⁶¹

Product liability insurance costs are substantially lower in foreign jurisdictions . . . foreign competitors often have product liability insurance costs that are 20 to 50 times lower than their U.S.-based competitors. Following the run-up in product liability insurance costs during 1985 and 1986, this competitive advantage may have increased even further.⁶²

Insurance costs are excessive in the biotechnology industry because judicial treatment of biotechnology products is uncertain and potentially very harsh. Uncertainty arises from the fact that the U.S. biotechnology industry has not yet been tested in terms of product liability lawsuits, probably due to the relatively small number of commercially viable biotechnology products marketed to date.⁶³

While courts see manufacturers as large economic institutions able to spread risks through the purchase of insurance and by passing on costs through higher prices to consumers, insurance is not always available. The viability of insurance is based on the predictability of risk, without which it becomes extremely difficult to underwrite risks. Large, unknown exposure causes insurers to withdraw entirely from the market. Thus, the judicial presumption that insurance is the "answer" is incorrect, as insurance companies are not more eager to lose their

58. *Id.* at 25.

59. Stephen D. Sugarman, *Doing Away with Tort Law*, 73 CAL. L. REV. 555, 582 (1985).

60. McGuire, *supra* note 49, at 3.

61. While it is true that foreign biotechnology producers must comply with U.S. law when marketing products in the United States, these producers do not confront the cost barriers to the development of biotechnology at home which product liability law has imposed on U.S. manufacturers. *Id.* at 4.

62. *Id.*

63. Currently, the FDA has approved only human growth hormone (treatment of dwarfism), insulin (treatment of diabetes), interferons and other lymphokines (treatment of immune deficiencies), monoclonal antibodies (treatment of cancer), and tissue plasminogen activator (treatment of myocardial infarction).

shirts to unpredictably generous injuries than are . . . manufacturers themselves.⁶⁴

Without on-point precedent applying strict product liability to biotechnology products, biotech firms must analogize from the litigation experience of related industries in order to predict judicial treatment of their products. Biotechnology manufacturers can derive no comfort from the experience of related industries, such as the vaccine industry. From the experience of the vaccine industry, which admittedly does not precisely address treatment of biotechnology products under strict liability theory,⁶⁵ it appears that biotechnology products will be subject to strict liability and its attendant repercussions.⁶⁶

Producers of vaccines have been hard hit by the unavailability of insurance coverage and increasing premiums.⁶⁷ For example, Wyeth Laboratories, a major manufacturer of whooping cough vaccine, recently withdrew from the market for that vaccine. Wyeth's withdrawal contributed to a potentially serious national DPT vaccine shortage and was precipitated by skyrocketing and unpredictable tort liability arising from lawsuits by victims of what are probably unavoidable side-effects of the vaccine.⁶⁸

Product liability costs have been cited as one of the most important reasons for the withdrawal of manufacturers from vaccine production.⁶⁹

64. Rosenfeld, *supra* note 52, at 195-96 (citing Robert G. Berger, *The Impact of Tort Law Development on Insurance: the Availability/Affordability Crisis and its Potential Solutions*, 37 AM. U. L. REV. 285, 300 (1988); *Safety and the Second Best*, *supra* note 33).

65. O'Reilly, *supra* note 1, at 474 n. 86.

66. Traynor & Cunningham, *supra* note 34 at 154:

The special relevance . . . to biotechnology is that biotech pharmaceutical companies are more likely than conventional pharmaceutical companies to confront these [cost] issues because biotechnology promises treatment of important diseases that conventional technologies have thus far not been able to address. Any technology that can produce important new therapies would confront these issues. Biotechnology just happens to be more capable of producing these therapies.

67. See, e.g., *Parke-Davis & Co. v. Stromsodt*, 411 F.2d 1390, 1392 (8th Cir. 1969) (\$500,000 award); *Tinnerholm v. Parke, Davis & Co.*, 411 F.2d 48, 50 (2d Cir. 1969) (\$651,758 award); *Sterling Drug, Inc. v. Yarrow*, 408 F.2d 978, 980 (8th Cir. 1969) (\$180,000 award). Under the Swine Flu Vaccination alone, 4,000 claims totalling \$2.95 billion have been filed. Of these 4,000 claims, \$1.91 billion have been denied, \$115 million (for a total of \$6.24 million) were settled before litigation and \$241 million (for a total of \$22 million) were settled only after litigation was initiated.

68. See *Davis v. Wyeth Labs., Inc.*, 399 F.2d 121, 129 (9th Cir. 1968); See also Stuart Taylor, *Product Liability: The New Morass*, N.Y. TIMES, Mar. 10, 1985, § 3, at 1. A report by the American Medical Association indicated that, in actuality, only 1 in 312,500 doses of whooping cough vaccine causes brain damage, 1 in 1,000,000 doses of measles vaccine causes brain damage, and 1 in 3.2 million doses of polio vaccine causes paralysis, mostly due to unvaccinated adults coming into contact with vaccinated children. *Safety and the Second Best*, *supra* note 33, at 285 n.35 (citing Philip M. Boffey, *Vaccine Liability Threatens Supplies*, N.Y. TIMES, June 26, 1984, at C1).

69. One commentator has stated:

[C]hildhood vaccine products liability cases have radically altered the vaccine market, as many manufacturers have simply been forced to discontinue production. As of 1984, only Merck,

The uncertain threat of strict liability strongly deters development of biotechnology products, like vaccines, which have a small but ineradicable probability of harm.⁷⁰

The threat of enormous and unpredictable liability continues to weigh heavily in our decisions relating to the development of new products and to improvements to existing ones. This is particularly significant in pharmaceuticals and other high-technology health-care products. In cases involving these products jurors are left free to second-guess the weight of impartial scientific opinion and the Food and Drug Administration, to find manufacturers at fault, and to award multi-million-dollar verdicts. As a result, valuable products whose potential profitability is outweighed by the risk of enormous liability never see the light of day.⁷¹

Even when manufacturers are not forced out of the industry by increasing insurance costs, continued judicial and governmental treatment may thoroughly stifle "development, mass-production, and distribution of new, safer vaccines."⁷² If the experience of the conventional vaccine industry represents an indication of the effects of strict product liability law, biotechnology producers will find it very difficult to take precautions against future liability and must continue to spend substantial resources to over-protect.⁷³

Our product liability system creates significant cost impediments to biotechnology innovation and product development. These impediments

Sharp & Dohne continued to produce the measles, mumps, and rubella (MMR) vaccine, and only Lederle and Connaught produced the polio and DPT vaccines . . . a government interagency task force estimated that one out of every six manufacturers had eliminated at least one product line as a result of liability concerns . . . [s]imilarly, in 1978, manufacturers refused to market an already developed influenza vaccine due to liability fears.

Rosenfeld, *supra* note 52, at 196-97 (citing *Vaccine Injury Compensation, 1984: Hearings on H.R. 556 Before the Subcomm. on Health and the Environment, 98th Cong., 2d Sess. 140, at 86-87 (1984)*; Richard Wilkinson, *Who Benefits from Product Tort Reform? You Do*, 60 *HOSPITALS* 86 (1986); Diane B. Lawrence, *Strict Liability, Computer Software, and Medicine: Public Policy at the Crossroads*, 23 *TORT & INS. L.J.* (1987)).

70. BIOTECH 90, *supra* note 2, at 92.

71. McGuire, *supra* note 49, at 18.

72. *Safety and the Second Best*, *supra* note 33, at 289.

There is no suggestion that Wyeth's whooping cough vaccine was more dangerous than any other United States manufacturer's. Wyeth and the others have simply encountered too much regulation in the courts. They have repeatedly been held liable for complications arising from the vaccine's use, and adequate insurance has become difficult to obtain. As a result, a manufacturer that increases national wealth ten-fold for every dollar of its product, one whose product contributes to saving hundreds of lives every year, has been forced by the tort system to abandon its product. There is every reason to fear that foolishness of this order, driven by the myopia of the judicial system, will continue.

Id.

73. McGuire, *supra* note 49, at 18.

[A] number of chief executives say that fear of liability has had a chilling effect on their companies' entire research effort While the evidence for the overall impact of liability on innovation is largely anecdotal, and there is no definitive measure of the dampening effect that fears of liability litigation may have on invention, testimony from various researchers as well as from executives supports the existence of such an impact.

Id.

derive in part from a lack of legal precedent applying strict product liability rules to biotechnology products. Increased insurance costs, decreased market share, and adverse effects on reputations for quality and reliability result from these impediments. Most importantly, capital and management resources are inefficiently diverted away from innovative research and product development projects. Biotechnology companies are, therefore, forced to utilize resources to protect against the possibility of claims, based upon fears derived from the experience of related industries such as the conventional vaccine industry, the bases of which are unforeseeable at the time of product development and sale.

B. Insurance Costs and "Temporal Stress"

Product liability insurance costs create barriers for U.S. biotechnology producers at the early stages of product development. The timing of these costs places a "temporal stress" on domestic biotechnology producers not experienced by foreign manufacturers and hinders entry into foreign and domestic markets thereby creating a limited market share and inability to spread costs.⁷⁴ Similar barriers do not confront foreign competitors.

As a result of significantly higher up-front insurance costs, U.S. producers of biotechnology products are at a distinct disadvantage in terms of the penetration of international markets. U.S. firms that may eventually seek to enter foreign product markets must still bear these up-front costs when manufacturing products domestically and face this additional layer of costs, which is not imposed upon foreign firms until much later in the commercialization process if and when they market their products in the U.S., before marketing can begin. Because most U.S. biotechnology companies market products primarily in domestic markets and have domestic principal places of business, they are subject to suit, and must therefore insure against the risk of suit, under U.S. product liability law. Although it appears that foreign manufacturers should be affected by the high costs of strict product liability which accompany the sale of products in the U.S. market, and its attendant litigation risks, and that U.S. biotechnology firms should expect to benefit from the reduced costs associated with the sale of products abroad, thus producing no net disadvantage to U.S. firms, this result is illusory. Foreign firms actually derive a significant competitive advantage over their U.S. counterparts due to the timing of the imposition of product liability costs with respect to firm maturity and financial viability.

U.S. biotechnology producers face the exorbitant costs of strict product liability now, at a time when most of these manufacturers are still considered to be small, financially immature, start-up companies without

74. See *infra* text accompanying notes 75-78.

established consumer bases. As a result, U.S. biotechnology manufacturers are precluded from developing *domestically*, the size and financial strength necessary to export products into foreign markets with more favorable and less costly product liability systems. By contrast, foreign biotechnology products are typically manufactured by larger, financially mature pharmaceutical firms with already-established international consumer bases that have developed under less costly domestic product liability systems. In short, when foreign firms seek to export biotechnology products to the U.S. market, they face the costs of U.S. strict product liability law from established positions characterized by the ability to meet these costs through cost-spreading and the reduction of already substantial profit margins.

In order to meet the increased direct and indirect costs associated with product liability, firms generally: (1) pass the costs on to consumers; (2) absorb the costs and reduce gross profit margins; or (3) choose a mix of consumer price increases and cost absorption.⁷⁵ However, most biotechnology firms cannot respond to increasing costs in this manner. Although long-term market potential for biotechnology products in all market segments is good,⁷⁶ small and mid-size biotechnology companies with limited market share cannot pass costs on to consumers in the short run by raising prices, or effectively absorb costs. Such firms risk short-term financial hardship as a result.⁷⁷ This is largely because (1) limited market share makes it impossible to pass costs on to a consumer base, and (2) absorbing the costs would reduce income statement profit margins, where they exist, which are used as a sign of fiscal health by firms seeking to raise growth capital. Moreover, reducing profit margins by absorbing the increased costs of product liability is not even feasible for most biotechnology companies, which are struggling to become profitable.⁷⁸ Most biotechnology companies cannot reduce profit margins to absorb product liability costs because they have yet to build such margins.⁷⁹

That most U.S. biotechnology firms must confront the costs of strict product liability at a time early in their development as financially viable enterprises is a significant difference between U.S. and foreign biotechnology manufacturers. This temporal distinction between the point in time, in terms of company development and financial viability,

75. McGuire, *supra* note 49, at 10.

76. BIOTECH 91, *supra* note 57, at 31.

77. *Proposed Remedies*, *supra* note 56, at 440.

78. In 1990, only 23% of all biotechnology companies were profitable. BIOTECH 91, *supra* note 57, at 78 (indicating that 31% of large firms, 28% of mid-size firms and 8% of small firms were profitable in 1990). For 1991, only 21% of all biotechnology firms were expected to be profitable. *Id.* (indicating that 23% of large firms, 24% of mid-size firms and 10% of small firms expected to be profitable in 1991).

79. Craig Torres, *Biotech Stocks are Bouncing Back*, WALL ST. J., July 20, 1992, at C1.

that product liability costs are imposed upon U.S. biotechnology firms and the point at which these costs are imposed upon foreign manufacturers is one major factor underlying the declining competitive advantage of U.S. biotechnology firms in relation to their foreign counterparts; and explains the illusion of no net disadvantage to U.S. biotechnology firms, mentioned above, resulting from the seeming offset of high domestic product liability costs and low foreign product liability costs. Changes must be made in the application of strict liability to biotechnology products in order to alleviate this early "temporal stress" upon U.S. biotechnology producers

IV. CONCLUSION

When one considers (1) the excessive costs imposed upon manufacturers, (2) the lack of legal precedent applying product liability law to biotechnology products and its resultant uncertainties, (3) the experience of the vaccine industry, and (4) the inability of biotechnology producers to meet product liability costs through cost spreading and/or the reduction of profit margins, the public policy goals of strict product liability are not served with respect to biotechnology.

Although the stated policy goals of strict product liability are the development of safer products and the provision of manufacturer-based social insurance, the excessive costs associated with strict product liability neither provide biotechnology manufacturers with incentives to develop safer products nor induce manufacturers to provide social insurance against the potential for harm from product use. Strict liability either impedes new product development or forces drastic price increases. Since the business of biotechnology firms is new product development—specifically, the development of products which are more effective and potentially safer than conventionally produced products—biotechnology manufacturers are placed in a "catch-22" by our system of strict product liability. As shown above, the excessive costs of a system designed to stimulate safety actually prohibit the development of new products which are potentially safer than their conventional counterparts. In essence, this is a barrier to entry. Further, most biotechnology firms do not yet have consumer bases or profit margins which make effective cost-spreading possible.⁸⁰ As a result, rather than achieving safer products and ensuring compensation for injured parties via cost-spreading, strict liability leaves many biotechnology firms unable to accomplish either

80. Other manufacturing industries, comprised of firms which do not have large consumer bases, may also be unable to effectively spread the costs of strict liability. Viable arguments against the continued application of strict liability to firms within other such industries, showing that well-defined policies underlying strict liability are not applicable to such industries, can be posed. This comment merely opposes application of strict liability to biotechnology firms.

objective.⁸¹ Because socially valuable products are lost to the market, the primary rationales for imposing strict liability break down with respect to biotechnology.

However, while many commentators and legislators now call for a drastic overhaul of the entire U.S. tort system, this comment espouses no such measures. Rather, this comment recommends industry-specific change in the application of U.S. product liability law that would improve the environment for the commercialization of biotechnology and help to restore the United States' competitive advantage in this critical industry.

First, the financial and competitive success of our biotechnology industry would be markedly enhanced through the discontinued use of the theory of strict product liability, as applied to causes of action involving biotechnology products, and the institution of a biotechnology-specific negligence standard. The establishment of a biotechnology-specific negligence standard in U.S. product liability law would provide a measurably greater level of protection for domestic biotechnology firms. Such a standard would have the effect of alleviating liability risks and the direct and indirect costs stemming from liability risks because, under this fault-based standard, liability would be significantly more difficult to establish than under strict liability. While any prediction as to whether such a proposal would find favor with legislators would be highly speculative, given the significant exposure that international competitiveness and tort reform has received recently, a statutory "exception" from strict tort liability for this nation's biotechnology producers seems to be a realistic proposal from both an economic and a political perspective.

Alternatively, a strengthening of the state-of-the-art defense and increased application of the "unavoidably unsafe" product defense⁸² to strict liability would provide biotechnology manufacturers with a measure of protection against the harsh results of strict liability. These defenses are necessary if biotechnology firms are to find any sort of relief from the burdens of liability fears and the costs related to protecting against the possibility of strict liability. In fact, the use of the unavoidably unsafe product defense may effectively reinstate a negligence standard.⁸³

81. See *Products Liability Reform*, *supra* note 47, at 370-74.

82. In *Brown v. Superior Court*, 751 P.2d 470, 477 (Cal. 1988), the California Supreme Court held that "... a drug manufacturer's liability for a defectively designed drug should not be measured by the standards of strict liability ... because of the public interest in the development, availability, and reasonable price of drugs, the appropriate test for determining responsibility is the test stated in comment k."

83. "[t]here is a general consensus that, although it [comment k] purports to explain the strict liability doctrine, in fact the principle it states is based on negligence." *Id.* at 475. Although *Brown* did not involve biotechnology products, Traynor and Cunningham suggest that the policy underlying the decision applies to biotechnology products as well as to conventional drugs. Traynor & Cunningham, *supra* note 34, at 167-72 (citing the *Brown* court's rejection of the risk-benefit analysis, case-by-case judicial determinations

For individual biotechnology producers and the U.S. biotechnology industry as a whole, the effect of such reforms will allow: (1) reduced liability-related direct and indirect costs due to diminished liability fears during innovation and development, (2) relatively uninhibited innovation and product development due to enhanced predictability in terms of the effects of product liability law on new and innovative products, and (3) ultimately, a substantially increased ability of U.S. biotechnology firms to compete in world markets due the diminution of the temporal stress created by excessive up-front costs. Until industry-specific reforms are made in U.S. product liability law in a conscious attempt to enhance the U.S. competitive advantage in biotechnology, product liability will continue to "loom as a disincentive of the innovation . . . which biotechnology's methods have promised to consumers."⁸⁴

and the consumer expectation test—all of which are inherent to strict product liability; and calling for the application of the *Brown* standard to biotechnology products).

84. O'Reilly, *supra* note 1, at 486.

