

ARTICLE

BIOTECHNOLOGY FOR HUMAN LIFE AND HEALTH— THE SPECIAL CASE FOR A NEGLIGENCE-ONLY RULE TO PROMOTE CRITICAL INNOVATION

ELEANOR M. FOX[†]
MICHAEL TRAYNOR^{††}

Table of Contents

I. INTRODUCTION.....	2
II. BIOTECHNOLOGY AND ALTERNATIVE LIABILITY RULES.....	3
III. THE LIMITS OF AMERICAN LAW.....	5
IV. AN EVOLUTION—TORT LAW, STRICT PRODUCT LIABILITY, AND COMMENT K.....	8
A. Strict Product Liability.....	8
B. Policy Advantages and Disadvantages of Strict Product Liability.....	10
C. Comment k—the Recognition that Strict Liability Should not Apply to All Products.....	10
D. Judicial Interpretation of Comment k.....	12
E. <i>Brown v. Superior Court</i> : A Blanket Exemption from Strict Liability for Prescription Drugs.....	14
F. The Aftermath of <i>Brown</i>	15
V. CANVASSING ALTERNATIVE LIABILITY RULES.....	19
A. The Case-by-Case Approach.....	19
B. A Negligence-Only Rule Through <i>Brown</i> or <i>Grundberg</i> , or a Primary Recognition of the Limits of Strict Liability.....	20

© 1991 Eleanor M. Fox and Michael Traynor

[†] Professor of Law, New York University Law School. LL.B. 1961, N.Y.U.; B.A. 1956, Vassar College.

^{††} Partner, Cooley Godward Castro Huddleson & Tatum. J.D. 1960, Harvard Law School; B.A. 1955, University of California at Berkeley.

The authors are indebted to Jonathan Galst, James B. Fuqua, Rene Pengra and Yvonne Gonzalez Rogers for their research assistance.

C. The Illusive Appeal to the Alternative Design Test.....	21
D. The Mechanics and Advantages of a Hospitable Negligence-Only Test.....	22
VI. THE SOCIAL RESPONSIBILITY TO KNOW, LEARN, AND FORESEE	23
VII. CONCLUSION.....	26

I. INTRODUCTION

Biotechnologically produced medical products are of exceptional value to humankind, and the research that produces them promises large spill-over benefits to human life and health. While biotechnology may seem to hold mysteries, scientists conclude that biotech medical products are no more dangerous than medical products made by conventional means. Indeed, they are likely to result in fewer by-product harms because of their unique ability to target diseased cells while not harming healthy cells.¹ The probable dynamic contributions of biotech research and product development should counsel hospitable legal rules.

Biotech products have not yet resulted in reported harm. When harm should occur and litigation should follow, plaintiffs are likely to invoke rules of strict product liability. Since biotech medical products are usually developed in the form of drugs and vaccines, jurists are likely to apply the legal rules applicable to other drugs and vaccines, or perhaps even rules of stricter liability.

We write this article in anticipation of such litigation. We reflect on the present state of the product liability system and ask whether the system is flexible enough to accommodate high technology, high social value products with positive spill-over benefits but some unforeseen and unforeseeable harms. This category might describe most traditionally made drugs and vaccines. It certainly describes biotech medical products.

The main conclusion of our article is that strict and quasi-strict product liability rules have a bias in favor of the status quo. They put extra costs on those who are foresightful and creative. While strict liability rules also have benefits, such as the internalization of costs and compensation for injured persons, the time has come to recognize a category in which the dynamic benefits lost by a regime of strict liability are likely to overwhelm the static benefits. Exactly where the two lines

1. See, e.g., Kolata, *In the War on Cancer, A New Kind of Weapon*, N.Y. Times, May 7, 1991, at B5, col. 1; S. BURRILL & K. LEE, *BIOTECH 91: A CHANGING ENVIRONMENT* 29 (1990) (referring to products such as tissue plasminogen activator, erythropoietin, alpha-interferon, human growth hormone, a hepatitis C blood test, and the introduction of a test for the cystic fibrosis gene). See also Fisher, *Biologists Re-Engineer Antibodies*, N.Y. Times, Mar. 5, 1991, at C1, col. 6.

cross is impossible to tell. But it is possible to begin the process of reining in strict and quasi-strict liability rules with a "best case" for a negligence-only rule governing the design of biotech medical products. A "best case" is a very high social value product with large positive spill-over benefits from the research and development that underlies the product.² Biotech medical products fit this description, and we argue here for a negligence-only rule, freed even from the case-by-case examination often accorded traditionally made drugs. In view of the hospitable treatment we urge for biotech medical products, we suggest that producers acknowledge their social and ethical responsibilities to discover and proceed upon early warning signals of danger and harm.

Section II of this article introduces certain biotechnologically designed products and alternative liability rules. Section III discusses the expansiveness of U.S. regulatory law and the search for limits. Section IV describes the evolution of tort law and the growing importance of the Restatement (Second) of Torts and comment k. Section V examines the costs and benefits of alternative liability rules. Finally, Section VI concludes with a note on social responsibility.

II. BIOTECHNOLOGY AND ALTERNATIVE LIABILITY RULES

On the frontiers of medical engineering, superior products are made with biotechnology, which involves the manipulation of living organisms.³ Biotechnology can substitute for traditional methods in the production of vaccines for humans, medical diagnostic products, veterinary medicines, and products to improve livestock and agricultural yields and quality. In medicine, biotechnology makes it possible to create drugs that target cell receptors precisely, changing the functions of diseased or distorted cells without touching the normal cells. As a result, biotechnologically-produced drugs are less likely to have debilitating side effects than are traditionally produced drugs.⁴

Biotech research has resulted in a number of important, currently available drugs, including: the first hepatitis-B vaccine; tissue plasminogen activator, a compound that dissolves blood clots developing after heart attacks and strokes; and human growth hormone, used as a

2. Another "best case" for reform in the same direction is the case of a high social value product that has been screened for safety by specified and competent administrative agencies. See *Grundberg v. Upjohn Co.*, 318 P.2d 89 (Utah 1991). See also *Wilson v. Piper Aircraft Corp.*, 282 Or. 61, 577 P.2d 1322 (1978) (Linde, J., concurring).

We do not deal centrally in this article with examples other than biotech medical products, but we encourage the search for similar examples.

3. See Kolata, *supra* note 1.

4. See *id.* See also Fisher, *supra* note 1.

substitute for natural hormone to help reverse infantile dwarfism.⁵ Biotechnology may also help to cure cystic fibrosis, the most common inherited fatal disease.⁶ Other currently researched biotech drugs may provide a cure for a number of different cancers.⁷ Biotech researchers are also studying a number of possible cures for AIDS.⁸ The President's Council on Competitiveness has singled out biotechnology as a principal area in which excessive government restrictions should be avoided.⁹

Like all products, biotech medical products may cause unexpected harms. We propose that liability for unforeseeable harms be imposed on the designer only if there was a failure to exercise due care.¹⁰ We argue that the imposition of strict liability as defined by section 402A of the Restatement (Second) of Torts,¹¹ or even a case-by-case inquiry to determine whether strict liability should apply, is likely to impose too high a cost on society in lost research and development to justify the rule.¹²

A narrower alternative would be to develop law within the context of comment k of Section 402A,¹³ which is interpreted as exempting certain

5. See *Biotechnology; The Promise and Peril of a New Age*, WorldPaper, Nov. 1990, at 10. See also Kolata, *supra* note 1.

6. See *Gene Therapy Cures Cystic Fibrosis in Lab*, Chicago Tribune, Sep. 21, 1990, at 1.

7. See *Biotech Firms Struggle to Turn Their Research into Healthcare*, San Diego Bus. J., Dec. 10, 1990, § 1, at 18. See also Kolata, *supra* note 1; Bernstein, *Genentech Tests Mab as Cancer Treatment*, 3 BIOWORLD 68 (Apr. 8, 1991) (reporting phase I clinical trials of monoclonal antibody to treat patients with breast and ovarian cancers).

8. See S. BURRILL & K. LEE, BIOTECH '92: PROMISE TO REALITY 14-20 (1991); Waldholz, *Gene Implants Destroy Cancer in Lab Rodents*, Wall St. J., Nov. 1, 1991, at B1, B8.

9. See *Competitiveness Council Biotechnology Study Says Japan, Europe Gaining on United States*, 8 Int'l Trade Rep. (BNA) 326 (Feb. 27, 1991).

Biotechnology has seldom been a subject of litigation. It was a subject of litigation, and was favorably treated, in *Moore v. Regents of the Univ. of Cal.*, 51 Cal. 3d 120, 793 P.2d 479, 271 Cal. Rptr. 146 (1990), *cert. denied*, ___ U.S. ___, No. 90-1037 (1991 WL 254322). The court considered whether Moore, a university hospital patient, had any basis for claiming compensation or restitution of the profits allegedly made by his treating physician, the university and others from a cell line developed from his surgically removed diseased spleen and patented and developed commercially without his explicit consent. It held that Moore can maintain a cause of action, not for conversion of property but for breach of a duty of disclosure of a physician's research or economic interests. See Dorney, *Moore v. The Regents of the University of California: Balancing the Need for Biotechnology Innovation Against The Right of Informed Consent*, 5 HIGH TECH. L.J. 333 (1990). For various perspectives on *Moore*, see *Symposium: Moore v. Regents*, 9 BIOTECH L. REP. 239 (1990).

10. We would not curtail liability in the case of a negligently designed product, since the threat of liability for negligence is an important incentive to make safe products.

11. See RESTATEMENT (SECOND) OF TORTS § 402A (1965) (strict liability applies to "product[s] in a defective condition unreasonably dangerous to the user").

12. We are not scientists, however, and we do not attempt to make the scientific case. This would require one to muster the data on availability of insurance, costs of insurance, size of jury awards, incidence of court or jury error (for example, in finding causation where it does not exist), or quantification of the benefits of innovation that would exist in the absence of ex post liability rules.

13. See *infra* text accompanying note 36.

products from strict liability. The problem with this approach is that it begins on the wrong foundation. It presumes that strict liability is the rule and that freedom from it is an exception. Moreover, the insistence on putting comment k into the center of the universe draws one into the highly contentious area of interpreting the quarter-century old text of a comment to a secondary source, rather than arguing on the basis of principle.

In a 1989 article,¹⁴ one of the present authors and a co-author argued that the rule of a then-recent California Supreme Court case,¹⁵ which construed comment k to exempt all prescription drugs from strict liability, should be applicable to the design of biotechnologically produced prescription drugs. In this article, we examine the state of the literature and jurisprudence two years later, and we build upon the previous article's proposal for a negligence-only rule. First, we take stock of the general problem of overregulation and the perceived need to scale back regulatory barriers that chill innovation.

III. THE LIMITS OF AMERICAN LAW

A quarter of a century ago the United States had an uncontested dominant economic position in the world. Today, America's power has faded.¹⁶ Its trading partners in Germany, Japan, Korea and elsewhere have absorbed large segments of American markets.¹⁷ Abroad, U.S. firms no longer present the feared "American Challenge" documented by J.J. Servan-Schrieber in his 1968 book.¹⁸

Many explanations have been offered for this fall from power of American business. Some analysts ascribe the phenomenon merely to the fact that our trading partners have finally recovered from the devastation of World War II, and competition is at last on a more equal footing.¹⁹ Others add that market power at mid-century brought complacency, and American business sat back on its laurels while Europe and Asia more than caught up.²⁰ Still others have asserted that "too much" law is a central problem of the United States. They argue that the fear of antitrust, tort and employee discrimination suits has stifled the innovation and

14. Traynor & Cunningham, *Emerging Product Liability Issues in Biotechnology*, 3 HIGH TECH. L.J. 149 (1989).

15. *Brown v. Superior Court*, 44 Cal. 3d 1049, 751 P.2d 470, 245 Cal. Rptr. 412 (1988).

16. M. PORTER, *THE COMPETITIVE ADVANTAGE OF NATIONS* (1990); F.M. SCHERER & D. ROSS, *INDUSTRIAL MARKET STRUCTURE AND ECONOMIC PERFORMANCE* (3d ed. 1990); R. REICH, *THE WORK OF NATIONS: PREPARING OURSELVES FOR 21ST CENTURY CAPITALISM* (1991).

17. *Id.*

18. J.J. SERVAN-SCHRIEBER, *THE AMERICAN CHALLENGE* (1968).

19. See B. FRIEDMAN, *DAY OF RECKONING: THE CONSEQUENCES OF AMERICAN ECONOMIC POLICY* (1989).

20. See F.M. SCHERER & D. ROSS, *supra* note 16.

efficiency of American firms, and that only radical surgery to cut back law will "free" American firms to compete in the world marketplace.

For antitrust and civil rights law, blame is put on the Warren Court for following the guiding light of pluralism, access and diversity at the cost of efficiency.²¹ For tort law, blame is put on "the Founders" of strict product liability.²²

As with Mark Twain's reflections on the rumors of his death, the claims of crisis are greatly exaggerated.²³ The rhetoric of crisis is often heard from individuals who do not like the core concept of strict liability.²⁴ Nonetheless, the critics of "expansive law" have spoken more than a germ of truth.

By about 1970 certain bodies of law, including torts and antitrust, had expanded beyond the bounds that their policy goals would justify. The expanded law undoubtedly deterred some socially progressive activity and increased the costs of available products.²⁵ Antitrust law

21. See, e.g., R. BORK, *THE TEMPTING OF AMERICA: THE POLITICAL SEDUCTION OF THE LAW* (1990); R. BORK, *THE ANTITRUST PARADOX: A POLICY AT WAR WITH ITSELF* (1978).

22. See, e.g., P. HUBER, *LIABILITY: THE LEGAL REVOLUTION AND ITS CONSEQUENCES* (1988).

23. See S. Clemens, *Cable From Europe to the Associated Press (1897)*, quoted in *BARTLETT'S FAMILIAR QUOTATIONS* 625 (15th ed. 1980). See Henderson & Eisenberg, *The Quiet Revolution in Product Liability: An Empirical Study of Legal Change*, 37 *UCLA L. REV.* 479 (1990).

24. See O.W. HOLMES, JR., *THE COMMON LAW, LECTURE III* (1881) (liability should be linked with personal responsibility; people should be liable only for what they could and should have prevented; more extensive law is an intrusion on personal freedom). For modern articulations of the same principle, see R. NOZICK, *ANARCHY, STATE, AND UTOPIA* (1974) and T.R. MACHAN, *INDIVIDUALS AND THEIR RIGHTS* (1989).

25. See T. DUNGWORTH, *PRODUCT LIABILITY AND THE BUSINESS SECTOR: LITIGATION TRENDS IN FEDERAL COURTS* (1988) (empirical study of the Institute for Civil Justice of the Rand Corporation); G. EADS & P. REUTER, *DESIGNING SAFER PRODUCTS: CORPORATE RESPONSES TO PRODUCT LIABILITY LAW AND REGULATION* 21 (1983); *Product Injuries*, in 1 *REPORTER'S STUDY TO THE AMERICAN LAW INSTITUTE, ENTERPRISE RESPONSIBILITY FOR PERSONAL INJURY* 255 (1991); *Product Defects and Warnings*, in 2 *REPORTER'S STUDY TO THE AMERICAN LAW INSTITUTE, ENTERPRISE RESPONSIBILITY FOR PERSONAL INJURY* 33 (1991); K. VISCUSI, *REFORMING PRODUCTS LIABILITY* (1991). See also *Browning-Ferris Indus. of Vermont, Inc. v. Kelco Disposal, Inc.*, 492 U.S. 257, 282 (1989) (O'Connor, J., concurring in part and dissenting in part) ("[t]he threat of such enormous [punitive damage] awards has a detrimental effect on the research and development of new products.").

Research along the foregoing lines may provide empirical data that will reinforce or explain or modify the intuitive judgment of the authors that strict liability tends to limit the availability of adequate and reasonably-priced liability insurance, to increase the exposure of young companies to liability they cannot sustain, and to impair incentives for research and innovation in health care. See Gastel, *Product Liability Tort Reform*, *INS. INFO. INST.* (April 1991) ("A 1988 Conference Board survey of 500 chief executive officers shows actual or threatened product liability suits caused 36 percent of surveyed companies to discontinue products, 15 percent to lay off workers and 8 percent to close plants"; also that a recent report of the AMA indicates that "several companies have stopped producing vaccines because of the threat of lawsuits"). See also Priest, *The Current Insurance Crisis and Modern Tort Law*, 96 *YALE L. J.* 1521 (1981); Giges, *Marketers Feel Product Liability Pressure: Risks Crimp Launch of New Items*, *ADVERTISING AGE*, May 12, 1986, at 3; OTA [Office of Technology Assessment] *Takes a Long Second Look at U.S. Role in Global Bio-Economy*,

provides good examples. The law expanded through judicial opinions particularly in the 1960s and early 1970s. By the 1970s many business persons feared that joint ventures among competitors might be illegal *per se*.

Responding to the problem of expansive antitrust law, the Supreme Court limited its excesses between the mid-1970s and the mid-1980s by working at its margins. In so doing, the Court tried to assure that the law would not chill conduct that promised the delivery of more, better or cheaper goods to consumers.²⁶

Special reform came in the area of high technology and innovation. Congress enacted the National Cooperative Research Act of 1984²⁷ to assure that R&D joint ventures would be facilitated and would not be condemned on their face. Also, the act reduced the quantum of damages available for certain R&D joint ventures that cause competitive harm. Moreover, in antitrust cases in general, courts began to err on the side of facilitating inventiveness rather than compensating plaintiffs.

We propose a similar course in product liability. Change should occur at the margin to induce important innovation, thus recreating an atmosphere hospitable to the prudent development of high social value products, particularly biotech products for medical uses. Tort law shall be preserved at the core of this system.

Biotechnology Newswatch at 8 (May 1, 1989); *Lawmakers Hear Call For Changes in U.S. Biopolicy*, BIOTECHNOLOGY NEWSWATCH, Jan. 6, 1986, at 4 (reporting comment by Warren C. Hyer, Managing Director of the Association of Biotechnology Companies, that without product liability insurance, the biotechnology company "is not only worried about its survival in the event of a lawsuit," but also "it can't enter clinical trials with medical institutions that require the producer to cover the risk of product problems").

The Institute for Civil Justice of the RAND Corporation has commenced a study of the economic effects of product liability law that is currently framed to include a case study of the pharmaceutical industry. It will focus on the factors that shape corporate perceptions of liability exposure and on the issue of how to measure the indirect effects of the liability system on corporate behavior. The ICJ may seek empirical data about what drugs were discontinued because of liability concerns; how information about potential liability exposure is communicated to research and developmental departments in drug companies; what research efforts were undertaken or stopped as a result of liability concerns; what information was furnished to the FDA and what correlation, if any, such disclosures and the FDA response have on a manufacturer's decision to pursue clinical testing or terminate research and investigation; the effect of the attenuation of the learned intermediary doctrine for certain drugs on the development of new drugs; and what drug companies' reactions are to changes in the law or to jury verdicts. (This paragraph is based in part on Mr. Traynor's awareness of the project as a member of ICJ's Board of Overseers and in part on his telephone conversation on May 9, 1991 with Mark Peterson, one of the researchers on the project.)

26. See Fox & Sullivan, *Antitrust—Retrospective and Prospective: Where Are We Coming From, Where Are We Going?*, 62 N.Y.U. L. REV. 936 (1987).

27. 15 U.S.C. §§ 4301–05 (Supp. II 1984).

IV. AN EVOLUTION—TORT LAW, STRICT PRODUCT LIABILITY, AND COMMENT K

There are lessons to be learned from contemplating expansive law. The major lessons are that law should not expand beyond its goals and that expansions should be worth their costs. The cost of lost innovation in medical products is high indeed. We turn, then, to the goals and evolution of tort law.

Tort law has several purposes. At first designed simply to resolve incendiary disputes in a fair and legitimate way, the early writ of trespass protected the integrity of person and property against direct invasions. People were liable for the harms they caused. But the law shifted to a negligence-only rule during the industrial revolution. Applying the philosophy of Oliver Wendell Holmes and encouraging the growth of railroads and industry, one court decreed that liability would fall on people and businesses only when they had the choice, the chance, and the moral imperative to prevent the harm they caused.²⁸

A. Strict Product Liability

In the mid-twentieth century, however, long past the pains of industrialization, a new need arose. Products were mass produced and mass distributed. Sometimes these products caused injuries to users, and victims demanded accountability. The new societal need was expressed nowhere more eloquently than by Justice (later Chief Justice) Roger Traynor, concurring in *Escola v. Coca-Cola Bottling Co.*:

Even if there is no negligence, however, public policy demands that responsibility be fixed wherever it will most effectively reduce the hazards to life and health inherent in defective products that reach the market. It is evident that the manufacturer can anticipate some hazards and guard against the recurrence of others, as the public cannot. Those who suffer injury from defective products are unprepared to meet its consequences. The cost of an injury and the loss of time or health may be an overwhelming misfortune to the person injured, and a needless one, for the risk of injury can be insured by the manufacturer and distributed among the public as a cost of doing business. It is to the public interest to discourage marketing of products having defects that are a menace to the public. If such products nevertheless find their way into the market it is to the public interest to place the responsibility for whatever injury they may cause upon the manufacturer, who, even if he is not negligent in the manufacture of the product, is responsible for its reaching the market. However intermittently such injuries may occur and however haphazardly they may strike, the risk of their occurrence is a constant

28. See M. HORWITZ, *THE TRANSFORMATION OF AMERICAN LAW 1780-1860* (1977); O.W. HOLMES, JR., *THE COMMON LAW* 77 et seq. (1881). See also Fox, *A Century of Tort Law: Holmes, Traynor and Modern Times*, Trial, July 1989, at 78.

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.²⁹

In Chief Justice Traynor's formulation, interests of efficiency, fairness, expectations, and legitimacy all coalesced. First, if the cost of defects in mass produced and distributed products were borne by the manufacturer, the manufacturer alone would have the necessary skill, knowledge, and incentive to make a safer product. Second, if the product bore its own costs, an externality would be internalized and price signals would be clearer and more efficient. Third, if the manufacturer paid the costs, justice to the manufacturer would be done in those cases where the manufacturer's negligence produced the defect but as a practical matter the victim could not prove it. In such cases, deterrence would be increased.³⁰ Finally, strict liability would serve the interests of compensating the victim, who normally did not have the chance to avoid injury from products that were placed in the stream of distribution.

The Chief Justice made the fair assumption that manufacturers subject to this new conception of product liability would be able to obtain insurance and to pay reasonable rates. The cost of accidents would therefore be borne and distributed efficiently by a company that would presumably continue to thrive if its product was useful. There was no reason to suppose that the manufacturer would not continue to produce or improve the product, for the profit was normally sufficient to induce the investment.

The Chief Justice's insight led to the modern rule of strict product liability, incorporated into Section 402A of the Restatement (Second) of Torts. Section 402A or some variant of it was adopted by state courts throughout the country. The general rule for product defects today is the rule of Section 402A, namely, that sellers of products are strictly liable for all harms proximately caused by their products' defects.³¹ The rule applies even if the seller has exercised all possible care.

It is now axiomatic that under a rule of strict product liability the focus of the inquiry is on the defective nature of the product rather than on the seller's conduct. If a plaintiff is able to prove that a product is defective and (in most jurisdictions) unreasonably dangerous, and that

29. 24 Cal. 2d 453, 462, 150 P.2d 436, 440-441 (1944). See also Traynor, *The Ways of Defective Products and Strict Liability*, 32 TENN. L. REV. 363 (1965).

30. The manufacturer would prefer to pay for the safety precaution than for the cost of injuries.

31. Section 402A provides:

(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 caused to the ultimate user or consumer to his property if

(a) the seller is engaged in the business of selling such a product, and
(b) it is expected to and does reach the user or consumer without substantial change in the condition in which it is sold.

the defect proximately caused an injury to the plaintiff, the seller is liable.³²

B. Policy Advantages and Disadvantages of Strict Product Liability

There are policy advantages to strict liability for all products, including biotech medical products. With a blanket strict liability rule, the standard of liability is clear. This leads to greater efficiency in investment decision-making and the conservation of judicial and litigation time.³³ Most importantly, the product internalizes the cost of its harms, and injured persons are compensated.

Moreover, it can be argued that victims are especially worthy of compensation in the case of harms from biotech products. Because of the newness and even perceived mysteriousness of biotechnology, which supposedly has prospects of causing science-fiction type misfortunes, victims may feel themselves to be "guinea pigs" of society.

On the negative side, however, products that bear the costs of strict liability necessarily cost more, which may make important medical products unaffordable. Also, the demand function may not allow the price increases necessary to cover the extra costs of insurance. Alternatively, insurance may become unavailable or insufficient and high tort judgments may force inventive firms out of the market, costing society the loss of investment in research, development, and production.³⁴ We will never know what pathbreaking products would have emerged in an environment more hospitable to inventiveness.

C. Comment k—the Recognition that Strict Liability Should not Apply to All Products

Since the adoption of the principle of strict product liability, the tension between the goals of promoting useful conduct and of

32. See *Brown v. Superior Court*, 44 Cal. 3d 1049, 751 P.2d 470, 245 Cal. Rptr. 412 (1980); *Toner v. Lederle Laboratories*, 112 Idaho 328, 732 P.2d 297 (1987); *Feldman v. Lederle Laboratories* 97 N.J. 429, 430, 479 A.2d 374, 375 (1984).

There are two accepted tests for proof of design defects. The consumer expectations test, as articulated in the Restatement, specifies that a product is unreasonably dangerous and therefore defective if it is more dangerous than would be expected by a reasonable consumer. See *RESTATEMENT (SECOND) OF TORTS* § 402A comment i (1965). The risk/benefit or danger/utility test specifies that a product is defective if the "magnitude of the danger outweighs the utility of the product." W. KEETON, D. DOBBS, R. KEETON & D. OWEN, *PROSSER AND KEETON ON THE LAW OF TORTS* 699 (5th ed. 1984). See also *Barker v. Lull Eng'g Co.*, 20 Cal. 3d 413, 573 P.2d 470, 143 Cal. Rptr. 225 (1978).

33. "It is much simpler to use a test for product actionability in strict liability design cases that avoids any issue of negligent conduct. The same position may be taken in the failure-to-warn cases." Wade, *On the Effect in Product Liability of Knowledge Unavailable Prior to Marketing*, 58 N.Y.U. L. REV. 734, 749 (1983).

34. See *supra* note 25.

compensating victims has been apparent. By definition, strict liability resolves the tension in favor of compensating victims. The resolution was apparently driven by an intuition that the cost of the trade-off in lost incentives would not be too great. For one category of products, however, the American Law Institute recognized that the cost of the trade-off *was* too great. To correct for this problem, the ALI adopted comment k in 1965.³⁵

Comment k states:

k. *Unavoidably unsafe products.* There are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use. These are especially common in the field of drugs. An outstanding example is the vaccine for the Pasteur treatment of rabies, which not uncommonly leads to very serious and damaging consequences when it is injected. Since the disease itself invariably leads to a dreadful death, both the marketing and use of the vaccine are justified, notwithstanding the unavoidable high degree of risk which they involve. Such a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it *unreasonably* dangerous. The same is true of many other drugs, vaccines and the like, many of which for this very reason cannot legally be sold except to physicians, or under the prescription of a physician. It is also true in particular of many new or experimental drugs as to which, because of lack of time and opportunity for sufficient medical experience, there can be no assurances of safety, or perhaps even of purity of ingredients, but such experience as there is justifies the marketing and use of the drug notwithstanding a medically recognizable risk. The seller of such products ... is not to be held to strict liability for unfortunate consequences attending their use, merely because he has undertaken to supply the public with an apparently useful product, attended with a known but apparently reasonable risk.³⁶

Unfortunately, the apparent purpose of comment k has been undermined and its implied limits ignored. The most plausible reason for the existence of comment k is a concern not to undercut the incentives to research, develop, produce and market products of high social value, especially medical products. The examples given of products to which comment k applies are drugs and vaccines, and the examples of risks are medical. The comment does not itself state why the products described should not be subject to the extra costs of strict liability. The reason is certainly not that drug and vaccine makers are less likely than other producers to be blameworthy; not only is there no reason to suspect that this proposition is true, but blameworthiness is by definition irrelevant to strict liability. The reason is not that injuries from "drugs, vaccines and the like" are unavoidable whereas injuries from other products, such as

35. RESTATEMENT (SECOND) OF TORTS § 402A comment k (1965).

36. *Id.*

asbestos, are avoidable. There is no basis for distinguishing degrees of avoidability. The reason is not that injuries caused by vaccines and drugs are more likely to be inherent in the product itself, even a perfectly made product, for the last sentence of the comment specifically includes the case of impurities in new drugs attributable to the lack of time to detect and remove the impurities.

The tone and examples of the comment lead to a rather simple conclusion: there are some products that are simply too critical to society to be burdened with the costs of accidents that are not the producer's fault. Tort rules should not delay the design, manufacture and sale of these products after the producer has taken all due care. The comment suggests that such products are not subject to strict liability under section 402A. It does not suggest the less favorable alternative of a presumptive strict liability rule with gateways for exemption. Much less does the comment reveal any indication that it was intended to someday gain the prominence of a statute. Still, the law has taken a turn in that direction.

D. Judicial Interpretation of Comment k

Over the years, a body of law developed regarding comment k's application to prescription drugs and vaccines, the closest analogy thus far to biotech medical cases. The courts adopted a case-by-case approach to comment k in both prescription drug and vaccine cases.³⁷ To avoid strict liability, the cases required the defendant to satisfy a two-pronged inquiry. First, the defendant had to prove³⁸ that it minimized risks and that the product was "incapable of being made safe given the present state of human knowledge."³⁹ Second, the defendant had to prove that on balance the product was socially beneficial⁴⁰ and that there was no safer alternative.⁴¹ This second prong is a risk/benefit test with a post hoc twist.⁴² A manufacturer "might be held strictly liable for harmful

37. See, e.g., *Patten v. Lederle Laboratories*, 676 F. Supp. 233, 236-37 (D. Utah 1987) (DPT vaccine); *Graham by Graham v. Wyeth Laboratories*, 666 F. Supp. 1483, 1496 (D. Kan. 1987) (DPT vaccine); *Ortho Pharmaceutical Corp. v. Heath*, 722 P.2d 410, 415 (Colo. 1986) (oral contraceptive); *Toner v. Lederle Laboratories*, 112 Idaho at 340, 732 P.2d at 308 (1987) (DPT vaccine); *Feldman v. Lederle Laboratories* 97 N.J. at 447, 479 A.2d at 383 (1984) (tetracycline).

38. The burden of proof has been placed on the seller. See, e.g., *Hill v. Searle Laboratories*, 884 F.2d 1064, 1068 (8th Cir. 1989) (IUD); *Allen v. G.D. Searle & Co.*, 708 F. Supp. 1142, 1149 (D. Or. 1989) (IUD); *Patten*, 676 F. Supp. at 237; *Toner*, 112 Idaho at 338, 732 P.2d at 302-03.

39. *Hill*, 884 F.2d at 1068.

40. In *Hill*, the court required defendant to prove that the product "possesses such a high degree of social need . . . that its use is warranted." *Id.*

41. See, e.g., *Allen*, 708 F. Supp. at 1149; *Patten*, 676 F. Supp. at 237; *Toner*, 112 Idaho at 337, 732 P.2d at 302-03.

42. The drug "must survive two risk/benefit challenges, first by the judge and then by the jury." *Brown v. Superior Court*, 44 Cal. 3d 1049, 1068, 751 P.2d 470, 482, 245 Cal. Rptr. 412, 424 (1980).

side effects because a trial judge could decide, perhaps many years later, that in fact another product which was available on the market would have accomplished the same result."⁴³

Many of the cases rely on *Toner v. Lederle Laboratories*,⁴⁴ the facts and analysis of which have contributed to an understanding of the jurisprudence of comment k. In *Toner*, a child received Tri-Immunol, a vaccination against diphtheria, pertussis and tetanus. The child suffered permanent damage to his spine and became paralyzed from the waist down.

According to the court in *Toner*, the manufacturer would be strictly liable unless it established three preconditions to gaining an exemption from strict liability under comment k. First, the manufacturer had to show that the product was "properly prepared, and accompanied by proper directions and warning." Second, it had to prove that the product's risk was "in fact unavoidable." Finally, it had to prove through a risk/benefit analysis that the product was one "apparently useful and desirable" for the public.

Despite the court's acknowledgment that strict liability could undermine incentives to develop new drugs,⁴⁵ it rejected blanket immunity from strict liability as an approach "counter both to the express language of comment k and to common sense."⁴⁶ Mixing ex ante and ex post considerations, the court declared that it did not "serve society that an unavoidably unsafe product, which has occasional or fractious benefit, should enjoy insulation from strict liability in tort when the product's predominant effects are detrimental to individual and public safety."⁴⁷

Ultimately, the court in *Toner* upheld a judgment on a jury verdict finding that the manufacturer did meet its burden in proving comment k exemption from strict liability. The court held, however, that the manufacturer could nonetheless be found negligent for marketing its DPT vaccine when it might have developed and sought FDA approval for a DPT vaccine prepared by a safer methodology.

The cases state that risk/benefit analysis should occur as of the time the product is distributed to the plaintiff. But clearly and by definition, the test is not a normal ex ante negligence test.

43. See *id.* at 1067-68, 751 P.2d at 482, 245 Cal. Rptr. at 423. See also, *Belle Bonfils Memorial Blood Bank v. Hansen*, 665 P.2d 118, 123 (Colo. 1983).

44. 112 Idaho 328, 732 P.2d 297 (1987). *Toner* was decided after the intermediate court decision but before the California Supreme Court had affirmed and expanded upon that decision in *Brown*.

45. *Id.* at 338-339, 732 P.2d at 307-308, (citing Schwartz, *Unavoidably Unsafe Products: Clarifying the Meaning and Policy Behind Comment k*, 42 WASH. & LEE L. REV. 1139, 1141 (1985) ("The public policy of encouraging the production of new and hopefully efficacious drugs is not compromised by imposing a reasonable standard on manufacturers to be responsible for new developments and risks in drugs they have marketed.")).

46. *Id.* at 340, 732 P.2d at 309.

47. *Id.* at 336-337, 732 P.2d at 305-06 (quoting Willig, *The Comment k Character: A Conceptual Barrier to Strict Liability*, 29 MERCER L. REV. 545, 575 (1978)).

Accordingly, under the widely adopted analysis of *Toner*, a drug or vaccine seller must compose a detailed defense in every tort action based on product design. In effect, the seller must jump the *Toner* hurdles to receive negligence-only treatment.⁴⁸

E. *Brown v. Superior Court*: A Blanket Exemption from Strict Liability for Prescription Drugs

In 1988 the California Supreme Court departed from the *Toner* approach in *Brown v. Superior Court*,⁴⁹ a consolidation of product liability cases against manufacturers of diethylstilbestrol ("DES"). The court rejected the usual case-by-case approach to determine whether DES was "unavoidably unsafe" within the meaning of comment k. It determined that prescription drugs that are designed with care but still cause harm are all unavoidably unsafe as a matter of law. The court concluded that prescription drugs are not subject to strict liability for allegedly defective design. The court's reasoning is particularly cogent:

Perhaps a drug might be made safer if it was withheld from the market until scientific skill and knowledge advanced to the point at which additional dangerous side effects would be revealed. But in most cases, such a delay in marketing new drugs—added to the delay required to obtain approval for release of the product from the Food and Drug Administration—would not serve the public welfare. Public policy favors the development and marketing of beneficial new drugs, even though some risks, perhaps serious ones, might accompany their introduction, because drugs can save lives and reduce pain and suffering.

If drug manufacturers were subject to strict liability, they might be reluctant to undertake research programs to develop some pharmaceuticals that would prove beneficial or to distribute others that are available to be marketed, because of the fear of large adverse

48. See 2 REPORTER'S STUDY TO THE AMERICAN LAW INSTITUTE, ENTERPRISE RESPONSIBILITY FOR PERSONAL INJURY 47-57 (1991); T. DUNGWORTH, *supra* note 25. See also Traynor & Cunningham, *supra* note 14.

In some jurisdictions, in design cases, strict liability can be avoided not only by comment k treatment but also or alternatively by proof of a "state of the art" defense. Some courts hold that a seller cannot be held liable for a defect that was undetectable given the state of scientific knowledge at the time the product was sold. Conversely, however, if detection was scientifically possible, the defendant would be strictly liable even though it did not know of the defect and exercised all due care. See, e.g., *George v. Celotex Corp.*, 914 F.2d 26 (2d Cir. 1990). Other jurisdictions reject a state of the art defense because such a defense introduces principles of negligence into areas carved out for strict liability. See, e.g., *Hayes v. Ariens Co.*, 462 N.E.2d 273, 277 (Mass. 1984); *Beshada v. Johns-Manville Products Corp.*, 90 N.J. 191, 202, 447 A.2d 539, 546 (1982) (asbestos).

49. 44 Cal. 3d 1049, 751 P.2d 470, 245 Cal. Rptr. 412 (1988). Doctors prescribed the drug to prevent miscarriages. Ingested during pregnancy, the drug allegedly caused injury to women *in utero* and to their offspring. The plaintiffs, the offspring of mothers who had used the drug during their *in utero* development, alleged that the manufacturers had knowledge that DES "contained a cancer-causing substance" and failed to warn consumers of the potential harm, as well as asserting no fault theories.

monetary judgments. Further, the additional expense of insuring against such liability—assuming such insurance would be available—and of research programs to reveal possible dangers not detectable by available scientific methods could place the cost of dedication beyond the reach of those who need it most.⁵⁰

F. The Aftermath of *Brown*

Since *Brown*, approximately a dozen states have interpreted comment k in strict liability claims involving drugs. Most of the published opinions deal with the question of whether a defendant-manufacturer can obtain a pretrial ruling, as in *Brown*, that strict liability is not applicable as a matter of law to the design of prescription drugs or medical devices. After *Brown* and until the Supreme Court of Utah decided *Grundberg v. Upjohn Co.*⁵¹ in 1991, the courts systematically ruled that the defendant-manufacturer can assert comment k as a defense to strict liability only after a case-by-case determination as to whether, for example, the product was unavoidably unsafe and had such high social value that it should be available despite the potential harm.⁵² Thus, the *Brown* rule rejecting the case-by-case approach and requiring a blanket negligence-only rule remains a distinct minority rule in the United States.⁵³ Moreover, in the aftermath of *Brown*, no judicial opinion other than *Grundberg* has given more than cursory discussion to the impact of strict liability on incentives in the prescription drug industry.

50. The court continued:

Dean Prosser summed up the justification for exempting prescription drugs from strict liability as follows:

The argument that industries producing potentially dangerous products should make good the harm, distribute it by liability insurance, and add the cost to the price of the product, encounters reason for pause, when we consider that two of the greatest medical boons to the human race, penicillin and cortisone, both have their dangerous side effects, and that drug companies might well have been deterred from producing and selling them.

44 Cal. 3d at 1063–1064, 751 P.2d at 479, 245 Cal. Rptr. at 420.

51. 813 P.2d 89 (Utah 1991).

52. *Hill v. Searle Laboratories*, 884 F.2d 1064, 1068–1069 (8th Cir. 1989); *Allen v. G.D. Searle & Co.*, 708 F. Supp. 1142, 1149–1150 (D. Or. 1989); *Kociemba v. G.D. Searle & Co.*, 695 F. Supp. 432, 435–436 (D. Minn. 1988); *Pollard v. Ashby*, 793 S.W.2d 394, 400 (Mo. App. 1990); *White v. Wyeth Laboratories, Inc.*, 40 Ohio St. 3d 390, 533 N.E.2d 748, 752 (1988); *Castrignano v. E.R. Squibb & Sons, Inc.*, 546 A.2d 775, 781 (R.I. 1988). The issue of the applicability of comment k may arise in a pretrial motion, for example, for summary judgment, and the court may decline to rule on the issue as a matter of law but remand to the jury to do a risk/benefit analysis.

53. See *Lindsay v. Ortho Pharmaceutical Corp.*, 637 F.2d 87, 90–91 (2d Cir. 1980) (oral contraceptives). But see *Jones v. Lederle Laboratories*, 695 F. Supp. 700, 706 (2d Cir. 1988) (involving DPT vaccine, the court suggested that the fact-finder must do a risk/utility analysis); *Moore v. Vanderloo*, 386 N.W.2d 108, 117 (Iowa 1986) (oral contraceptive); *McKee v. Moore*, 648 P.2d 21, 23 (Okla. 1982) (IUD); *Terhune v. A.H. Robins Co.*, 90 Wash. 2d 9, 16–17, 577 P.2d 975, 979 (1978) (IUD).

Grundberg involved several causes of action in negligence and strict liability against Upjohn, the manufacturer of the drug Halcion. Ilo Grundberg was taking Halcion to treat her case of insomnia. Consistent with Upjohn's recommendations, Grundberg's doctor prescribed a dosage of .5 milligram. When Grundberg took the drug at this dosage, she allegedly experienced intoxication, depersonalization, and homicidal compulsion. While suffering from these side-effects, Grundberg shot and killed her mother.

The personal representative of the mother's estate sued Upjohn in federal court. The federal court certified to the Utah Supreme Court the questions: Does Utah adopt the "unavoidably unsafe" exemption to strict product liability as set forth in comment k, and if so are all FDA-approved prescription drugs within the "unavoidably unsafe" exemption as a matter of law, or should the determination be made on a case-by-case basis?

The Court did adopt the "unavoidably unsafe" exemption and agreed with *Brown's* rejection of the case-by-case approach. For prescription drugs approved by the FDA, the court held that:

In light of the strong public interest in the availability and affordability of prescription medication, the extensive regulatory system of the FDA, and the avenues of recovery still available to plaintiffs by claiming inadequate warning, mismanufacture, improper marketing, or misrepresenting information to the FDA, we conclude that a broad grant of immunity from strict liability claims based on design defects should be extended to FDA-approved prescription drugs in Utah.⁵⁴

But *Grundberg* criticized *Brown's* "apparent attempt to use the plain language of comment k as the vehicle for exempting all prescription drugs from strict liability rather than relying on the policies underlying that comment."⁵⁵ Arguing on the basis of comment k's underlying policies, the court stated:

Because prescription drugs are chemical compounds designed to interact with the chemical and physiological processes of the human body, they will almost always pose some risk of side effects in certain individuals. Despite these risks, new drugs are continually approved by the FDA because of their social benefit in saving lives and alleviating human suffering. The health care system and general standard of living in this country, for example, would be seriously impaired without such essential drug products as antibiotics that allow quick recovery from ailments that were once debilitating or even fatal....

54. 813 P.2d at 99. It bears noting that the FDA has a "volume of new products in the pipeline," including many that "are much more complex scientifically than their earlier counterparts." *Biotech Pipeline: Bottleneck Ahead*, 254 SCIENCE 369 (1991). Reliance on the FDA regulatory system will require resources sufficient to the task.

55. 813 P.2d at 95.

Despite inherent risks, *and in contrast to any other products*, society has determined that prescription medications provide a unique benefit and so should be available to physicians with appropriate warnings and guidance as to use. The federal government has established an elaborate regulatory system, overseen by the FDA, to control the approval and distribution of these drugs.... No other class of products is subject to such special restrictions or protections in our society (emphasis added by court).⁵⁶

Most post-*Brown* cases involve actions for harms allegedly caused by DPT (the generic name for a vaccine against diphtheria, tetanus, and pertussis),⁵⁷ DES (diethylstilbestrol),⁵⁸ Chymodictin,⁵⁹ Myelogram,⁶⁰ Bendectin,⁶¹ Carbamazepine,⁶² Keflex,⁶³ and oral polio vaccine.⁶⁴

Many other post-*Brown* cases involve G.D. Searle & Co., which designed and manufactured the Copper-7 (Cu-7) IUD.⁶⁵ The IUDs allegedly caused permanent infertility,⁶⁶ pelvic inflammatory disease

56. *Id.* at 95, 96.

57. *White*, 40 Ohio St. 3d 390, 533 N.E.2d 748 (1988) (affirming court of appeals reversal of a jury verdict for plaintiff; adopting a case-by-case approach); *Ackley v. Wyeth Laboratories, Inc.*, 919 F.2d 397 (6th Cir. 1990) (summary judgment affirmed on issue of negligent design pursuant to *White*).

58. *Castrignano v. E.R. Squibb & Pons, Inc.*, 546 A.2d 775 (R.I. 1988) (adopting case-by-case approach to application of comment k in design-defect cases). On remand, jury found defendant liable. *Castrignano v. E. R. Squibb & Pons, Inc.*, 900 F.2d 455 (1st Cir. 1990); *Shirkey v. Eli Lilly & Co.*, 852 F.2d 227 (7th Cir. 1988).

59. *Pollard v. Ashby*, 793 S.W.2d 394 (Mo. App. 1990) (divided court affirms jury verdict for plaintiff and rejects *Brown*; argues that the ALI rejected a blanket provision in drafting Section 402A and comment k).

60. *Savina v. Sterling Drug, Inc.*, 247 Kan. 105, 795 P.2d 915 (1990) (adopting a case-by-case determination and applying comment k to the drug; remanded on issue of warnings).

61. *Daubert v. Merrell Dow Pharmaceutical*, 711 F. Supp. 546 (S.D. Cal. 1989) (motion for summary adjudication of issues denied on issue of failure to warn). *See also* *Coyle v. Richardson-Merrell, Inc.*, 526 Pa. 208, 584 A.2d 1383 (1991).

62. *Williams v. Ciba-Geigy Corp.*, 686 F. Supp. 573 (W.D. La. 1988), *aff'd*, 864 F.2d 789 (5th Cir. 1988) (summary judgment for manufacturers upheld; rejected plaintiff's theory that Carbamazepine was "unreasonably dangerous per se" and therefore that its risk was always greater than its utility).

63. *Jacobs v. Dista Products Co.*, 693 F. Supp. 1029 (D. Wyo. 1988) (failure to warn at issue).

64. *Snawder v. Cohen*, 749 F. Supp. 1473 (W.D. Ky. 1990) (failure to warn at issue).

65. On February 25, 1974, the Food and Drug Administration ("FDA") approved the Cu-7 IUD as a drug because it contains copper, a heavy metal. The Cu-7 IUD is an intrauterine copper strand used as a contraceptive and available through a physician's prescription only. The physician inserts the apparatus into a woman's uterus through the vagina and cervix where it remains until a physician removes it. At the time of its introduction, many women across America had ceased using oral contraceptives because of publicity regarding side effects. *Hill v. Searle Laboratories*, 884 F.2d 1064, 1065 (8th Cir. 1989) (referencing *Statement of Russell J. Thomsen, M.D., Hearings on Intrauterine Contraceptive Devices Before Subcomm. of the House Committee on Government Operations*, 93rd Cong., 1st Sess. (1973)). *See also*, *Allen v. G.D. Searle*, 708 F. Supp. 1142, 1145 (D. Or. 1989) (motion for summary judgment denied; case-by-case determination accepted); *Amore v. G.D. Searle*, 748 F. Supp. 845, 847 (S.D. Fla. 1990) (motion for summary judgment denied; case-by-case determination accepted).

66. *See Amore*, 748 F. Supp. at 847.

including pelvic pain and bleeding, and infection of the upper genital tract including the uterus, fallopian tubes, and ovaries.⁶⁷ Also, it is alleged in some IUD cases that the polypropylene removal string retracted into the uterus.⁶⁸ In all of these cases, courts refused to take a blanket approach to comment k, citing the history and language of the comment and the need for a strict liability type of risk/benefit analysis.

These post-*Brown* opinions assert that the language of comment k necessitates a limited scope for derogation from Section 402A and that the language specifically precludes a blanket exemption. They posit that comment k states its own test⁶⁹ which indicates that not all drugs are worthy of exemption from strict liability.⁷⁰

While the formulations in the various opinions contain different nuances, each court attempts to determine whether the social utility of the product outweighs its risk to society. Some of the opinions rely heavily on the history of comment k (much like one would rely on legislative history) to aid in construction.⁷¹ Some jurists note that a blanket exemption for prescription drugs was proposed at an American Law Institute meeting and that that the motion was defeated.⁷² They conclude that the drafters must have intended comment k not to offer such an exemption. These jurists parse the language in the comment the way one would parse statutory language, instead of recognizing the comment as elaboration on a principle in a secondary source that is under constant common law development. Thus, comment k becomes not only the freeze-dried product of an annual meeting of the ALI never to evolve in light of current needs, but it is frozen law. Meanwhile, the ALI itself rejects the notion of treating the Restatement as a statutory code.⁷³

67. *Allen*, 708 F. Supp. at 1145.

68. *Adams v. G.D. Searle*, 16 Fla. L. Week 233, 1991 WL 3575 (1991) (reversed summary judgment for defendant holding that comment k involves a mixed question of law and fact to be determined by the jury).

69. They argue that the comment requires manufacturers to show that the product was "incapable of being made safe," that it was "properly prepared and marketed," and that a "proper warning" was issued. *Amore*, 748 F. Supp. at 854.

70. The comment refers to "some products" which are incapable of being made safe. It states that these products are "especially common in the field of drugs." The post-*Brown* opinions note that when comment k states that certain products are not unreasonably dangerous, the comment explains "the same is true of *many* other drugs" (emphasis added) and "*many* new or experimental drugs." (emphasis added). The cases draw a negative inference from this wording that comment k was not intended to exclude *all* drugs from strict liability. See, e.g., *White v. Wyeth Laboratories, Inc.*, 40 Ohio St. 3d 390, 533 N.E. 2d 748 (1988). See also RESTATEMENT (SECOND) OF TORTS § 402A comment k (1965).

71. See, e.g., *Hill v. Searle Laboratories*, 884 F.2d 1064 (8th Cir. 1989); *Amore*, 748 F. Supp. at 854.

72. *Amore*, 748 F. Supp. at 854 (citing 38 ALI Proc. 19, 90-98 (1961)).

73. REPORT OF COMMITTEE ON ESTABLISHMENT 29, 45 (1923), reprinted in THE AMERICAN LAW INSTITUTE—50TH ANNIVERSARY (1973) ("legislative enactment of the restatement as a code of law not desirable"); Wechsler, *The Course of The Restatements*, 55 ABA J. 147, 150 (1969) (Restatements are "a modest but essential aid in the improved analysis,

V. CANVASSING ALTERNATIVE LIABILITY RULES

Having examined the evolving and sometimes inconsistent law on drugs and vaccines, which is the closest analogy to biotech medical products, we find it useful to step back and consider costs and benefits of alternative liability rules. There are several possible approaches to the liability rules for biotech medical products. One is blanket strict liability. This rule would be harsher than the usual rule applied to drugs and vaccines and could be justified only by a claim that biotech medical products are more inherently dangerous and hold more net costs than traditionally produced drugs and vaccines. Yet, this claim has not been made.

The second is case-by-case analysis wherein the defendant must prove that the harm was unavoidable, that the product is socially valuable, and that there is no safer alternative. The third is a negligence-only rule for all biotech medical products. Here, we compare the second and third alternatives on the supposition that they will be the alternatives most seriously entertained.

A. The Case-by-Case Approach

The principal advantage of the case-by-case approach is that some injured persons recover from a non-negligent producer or seller. The problems, however, are numerous: (1) Invention is deterred by the added costs of possible strict liability. (2) Investment decisions are inefficient because the investor in innovation cannot know in advance what rule of law will apply to the outcome. (3) Judicial proceedings are long, complicated and expensive, and are likely to yield inconsistent results, causing a perception of illegitimacy of the process. (4) The substantive inquiry is not principled. It is a hybrid between *ex ante* and *ex post* considerations.

The substantive inquiry does not examine duty and breach but the social value of the product, the theoretical avoidability of unpredictable harm, and the rejection of a safer product even if one's own product was not known to be unsafe and might have appeared more innovative than an available alternative. Since knowledge of the rule of law is not expected to induce greater care, the inquiry is merely a tool used to locate an arbitrary line on one side of which injured persons recover from non-negligent sellers and on the other side of which they do not.

The weightiest disadvantage of the case-by-case approach is the chill it places on inventiveness (although less so than a pure strict liability

clarification, growth and adaptation of the common law"); Perkins, *The Genesis and Goals of the ALI Corporate Governance Project*, 8 CARDOZO L. REV. 661, 684 (1987) ("No ALI Project has served to 'freeze' the law"). See also *Grundberg v. Upjohn Co.* 813 P.2d 89, 95 (Utah 1991).

approach). The court in *Toner* attempted to address this problem by stating that if shortages of drugs occur or new development is stifled one "would expect the Legislature to intervene to prevent the resulting health crisis."⁷⁴ But the possibility of legislative intervention at times of crisis cannot compensate for stifled innovation. Moreover, one cannot realistically expect legislatures to intervene or legislative solutions to be adequate in the case of every incipient health crisis. More importantly, in a regime that suppresses research, we may never know how to prevent health crises when they occur. We will never know what cures to what diseases would have been discovered. The new "penicillin" may never be invented. The research dollars will never have been committed.⁷⁵

B. A Negligence-Only Rule through *Brown* or *Grundberg*,⁷⁶ or a Primary Recognition of the Limits of Strict Liability

A negligence-only rule for the design of biotech medical products will increase research, development, and production of these socially vital products, thus saving human suffering and human lives. Second, it will avoid the expense and waste of case-by-case determinations. Third, the rule will legitimize law and process because the rule is a principled one.

The disadvantage of this rule is that the victim will not be compensated by the non-negligent seller. Whether individuals who suffer personal injuries should have their medical expenses allayed (e.g., through national health insurance) is a remaining question. Here, we only suggest that the rule of compensation *from the seller* should be trumped when such a rule is likely to lead to more human suffering than a rule of no compensation from the seller.

C. The Illusive Appeal to the Alternative Design Test

Much has been written about product design in general and the resemblance of risk/utility tests to negligence tests, at least if analysis is not *ex post*. Moreover, many analysts have expressed concern that strict liability rules unduly impair incentives to invent. In view of potential costs of strict liability, the American Law Institute authorized a study on Enterprise Responsibility for Personal Injury. In their study, the reporters

74. *Toner v. Lederle Laboratories*, 112 Idaho 328, 343, 732 P.2d 297, 312 (1987). *But cf.* L. KIRP & H. MAHER, THE POLITICS OF THE AIDS VACCINE OR HOW THE CALIFORNIA LEGISLATURE SEARCHED FOR THE MAGIC BULLET—AND WOUND UP SQUABBLING WITH THE TRIAL LAWYERS, THE BUDGET CUTTERS AND THE ALZHEIMER'S ESTABLISHMENT, (Institute of Governmental Studies, Univ. of Calif. at Berkeley, Working Paper No. 87-7, 1987).

75. *Cf.* Easterbrook, *The Limits of Antitrust*, 63 TEX. L. REV. 1 (1984); Jorde & Teece, *Innovation, Cooperation and Antitrust*, 4 HIGH TECH. L.J. 1 (1989). *See also supra* note 25.

76. Both *Brown* and *Grundberg* rely on comment k. Accordingly, they speak in terms of "immunity" from strict liability. A more open negligence rule would not start with strict liability as the main case, and freedom from strict liability would not need justification.

stated: "Because a producer is liable only if it balances risks and utilities incorrectly, the risk/utility test is not a true strict liability test, but rather looks much like legal negligence with a state of the art defense substituted for an explicit foreseeability requirement."⁷⁷ The Reporters propose the following substitute for the current risk-utility test:

A product's design should be deemed defective if and only if there was a feasible alternative design which, consistent with the consumer's expected use of the product, would have avoided the particular injury, and if the costs of the alternative design are less than the costs of the injuries thereby avoidable.⁷⁸

While at first blush the Reporters' suggestion might seem a reasonable compromise between the *Toner* case-by-case approach and a pure negligence-only rule, on a closer look the proposal incorporates some of the static elements of the *Toner* test and it would not provide the most enlightened principle for biotech products. Under the test, innovative change must be justified in view of what exists, rather than encouraged in view of what might be. The test ignores the fact that a new product may have appeared more promising than existing alternatives, and it may have promised positive spill-over benefits by opening new paths for innovation. If all creative people had to justify change, progress would be stopped in its tracks. It is impossible to optimize innovation by anchoring it to the status quo.⁷⁹ To foster research and design of new biotech medical products, biotech companies should not be required to prove that a biotech design is preferable to an existing conventional design.⁸⁰

D. The Mechanics and Advantages of a Hospitable Negligence-Only Test

We prefer a negligence test that asks simply whether the biotech medical product "was properly prepared and accompanied by warnings of its dangerous propensities that were either known or reasonably scientifically knowable at the time of distribution."⁸¹ Such a test

77. 2 REPORTER'S STUDY TO THE AMERICAN LAW INSTITUTE, *supra* note 25, at 48.

78. *Id.* at 56.

79. The test also suffers from a peculiar mixture of ex post and ex ante analysis. The injury in suit is taken as a given although it may not have been foreseeable. If the product of alternative design would not foreseeably cause the same injury, the fact-finder would undoubtedly find that its use *would* have avoided the injury. Yet, ex ante, the alternative design may not have been safer. Moreover, the design in suit and the underlying technology for it may have held benefits beyond those promised by the alternative design.

80. Compare Traynor & Cunningham, *supra* note 14 at 178, 185-187 with O'Reilly, *Biotechnology Meets Products Liability: Problems Beyond the State of the Art*, 24 Hous. L. Rev. 451, 460-61, 477-78 (1987). Cf. Editorial, *Keep Medical Technology Healthy*, N.Y. Times, May 18, 1991, at 22, Col. 1.

81. *Brown v. Superior Court*, 44 Cal. 3d 1049, 1069, 751 P.2d 470, 483, 245 Cal. Rptr. 412, 424 (1988).

harmonizes with the standard negligence test articulated by the Restatement (Second) of Torts that "negligence is conduct which falls below the standard established by law for the protection of others against unreasonable risk of harm."⁸²

The flexibility of the standard⁸³ is a virtue, because "unreasonable risk" is a concept well developed by the case law. Under such a standard, an unjustified departure from a manufacturer's design protocol, industry custom, or an FDA requirement would be negligent, as would a manufacturer's failure to provide adequate warnings. Under the same standard, bringing to the market an innovation that promises more benefit than harm would be non-negligent. A person might be injured and might claim and prove that the use of a different product would probably have avoided the harm, but this is a fortuity and would not be a basis for liability. Research and innovation beneficial to human health are more likely to flourish under the negligence-only standard than under either a strict liability regime or its complicated "alternative design," risk/utility, or other case-by-case variants.

To illustrate, let us imagine the case of a hypothetical biotech vaccine. Instead of using a killed virus or an attenuated live virus, a biotech vaccine manufacturer may attempt to replicate the virus by engineering only that portion of it that triggers the body's immune response. Only the portion of the virus that stimulates the immune system would be produced, not the infectious portion.⁸⁴ For this reason, the vaccine itself may present no risk or virtually no risk to the recipient.⁸⁵ The manufacturer may determine that the "subunit" vaccine should be accompanied by a substance commonly called an "adjuvant" that will enhance the immune response.⁸⁶ Conventional choices include

82. RESTATEMENT (SECOND) OF TORTS § 282 (1965). See also *Brown*, at 283, 285, 289, 290, 291, 292, 293.

83. See W. KEETON, *supra* note 32, at 193 ("the application of this standard of reasonable conduct is as wide as all human behavior").

84. Traynor & Cunningham, *supra* note 14, at 161.

85. *Id.*

86. See R. HYDE & R. PATNODE, *IMMUNOLOGY* 65 (1987): "Enhancement of the immune response can be affected by increasing the rate at which the response occurs, elevating its magnitude, prolonging the response, or directing the response to a particular facet of the immune response. Substances capable of these actions may be specific or nonspecific potentiators. Nonspecific potentiators are called adjuvants. Adjuvants are substances that enhance the immunogenicity of molecules without altering their chemical composition. Adjuvants enhance immune response by their ability to increase the efficiency of macrophage processing of antigen, prolong the period of exposure to the antigen, and amplify the proliferation of immunologically committed lymphocytes." See also I. ROITI, *ESSENTIAL IMMUNOLOGY* 180-82 (6th ed. 1988); Tilton, *Vaccines Get Booster from High Technology*, *CHEMICAL MARKETING REP.*, SR27 (Mar. 19, 1990).

The U.S. Patent and Trademark Office has recently issued a patent to Cambridge Biotech Corporation for an adjuvant that the company plans to use for its recombinant subunit vaccine against feline leukemia and in connection with preclinical studies to determine the feasibility of using the adjuvant in human vaccines against diseases like

Freund's adjuvant⁸⁷ and alum.⁸⁸ To increase potency and avoid known side effects of these adjuvants, the manufacturer may wish to instead create and use a biotech adjuvant.

Under a pure negligence-only rule, the manufacturer's choice of a biotech adjuvant would not need to be justified by comparison to the "alternative design" of Freund's adjuvant or alum or any other conventional product. The choice would be tested under the negligence standard of unreasonable risk, which always takes into account existing alternatives and prominently takes into account the manufacturer's care in following its design protocol, industry custom and applicable regulations, and the provision of adequate warnings. Significantly, the standard also takes into account the general and particular probable benefits of the innovative activity, especially the probable spill-over benefits to life and health.

VI. THE SOCIAL RESPONSIBILITY TO KNOW, LEARN, AND FORESEE

Biotechnology is imagined to hold mysterious risks.⁸⁹ If the benefits we expect from medical biotech products are much greater than the harms, liability and related rules should lean decisively on the side of facilitating non-negligent medical biotech development. At the same time, however, we are mindful of the unproud history of product after product from companies whose executives and spokespeople have refused to "know" of the harms their products cause long after the connections are, at first, suspicious, and later, barely contestable. Tobacco and asbestos are notorious examples.⁹⁰

malaria, herpes, certain forms of hepatitis, and even AIDS. N.Y. Times, Oct. 19, 1991, § 1, at 36, col. 5.

87. "Freund's adjuvant is a classic adjuvant that is an emulsion of paraffin or mineral oil (usually Bayol F) and water. Lanolin and arlocel A are used as emulsifying agents." See R. HYDE & R. PATNODE, *supra* note 86.

88. "Aluminum hydroxide and alum have a mechanism of action similar to Freund's adjuvant in retarding absorption of the antigen and thus prolonging exposure to antibody-forming tissues. They will also cause local inflammation, thus increasing mononuclear cell exposure." *Id.* at 66.

89. See S. NOVICK ET. AL., *LAW OF ENVIRONMENTAL PROTECTION* §§ 18-9 to 18-19 (1987).

90. See *The Effect of Cipollone: Has the Tobacco Industry Lost its Impenetrable Shield?* 23 GEORGIA L. REV. 763 (1989) (discussing *Cipollone v. Liggett Group*, 893 F.2d 541 (3d Cir. 1990), *cert. granted*, ___ U.S. ___, 111 S. Ct. 1386 (1991)).

See Nelson-Horchler, *Dodging the Liability Bullet*, *INDUSTRY WEEK* 30 (Apr. 6, 1987) (asbestos manufacturers were aware of the products' hazards as early as the 1930s, yet failed to provide workers with handling instructions or safety equipment, or to label the products as dangerous). See also *Beshada v. Johns-Manville Prod. Corp.*, 90 N.J. 191, 447 A.2d 539 (1982); *Hardy v. Johns-Manville Sales Corp.*, 681 F.2d 334 (5th Cir. 1982).

See Seltzer, *Punitive Damages in Mass Tort Litigation: Addressing the Problems of Fairness, Efficiency and Control*, 52 FORDHAM L. REV. 37, 51-55 (1983) (MER/29, used in the treatment of high cholesterol, was found to cause cataracts. Richardson-Merrell, the drug's

To be entitled to the respectful treatment we recommend, it would be incumbent upon the biotech companies to recognize their social responsibility. They should be held to high standards of quality assurance, including audits of raw material suppliers, testing and staff training. They should be constantly alert to receive and process information linking biotechnological methodologies to harms. They should be held to the highest obligation to prevent false and misleading denials, and to shun all cover-ups.⁹¹ They should recognize their duty to investigate early warning signals, and to cause information to be published and disseminated, not bottled up. Product labeling and warnings should be monitored and updated carefully. Unbiased individuals should be in charge of analyzing all claimed linkages of biotech methodologies to harm. Before harm happens, medical biotech companies should examine and develop standards regarding what constitutes evidence of a meaningful causal linkage and what constitutes a warning signal. Before harm happens, the companies should formulate standards for identifying information that should be aired, and plans for disseminating and acting upon it. Such standards, plans and policies of forthrightness will enure not only to the benefit of the public,⁹² but to the benefit of the biotech industry as well.⁹³

Social responsibility also entails pricing at levels that are not exorbitant. Certain scarce drugs, including biotech drugs, sell for thousands of dollars per dose. In 1989 AZT, the only drug licensed to treat AIDS, cost each patient approximately \$8,000 for "usual" yearly doses. Protesters claim that the AZT manufacturer is earning unconscionable profits by charging such a high price for the drug.⁹⁴

manufacturer, was found criminally liable for making false and fraudulent statements to the FDA regarding the drug's hazards. Richardson-Merrell was subsequently held liable for more than \$200 million in damages in civil suits by injured persons.) See also Roginsky v. Richardson-Merrell, 378 F.2d 832 (2d Cir. 1967).

See *Memo in Ray Case Warned of AIDS Link*, United Press International, May 18, 1990, Tampa, Fl. (internal memorandum dated Dec. 1982 at blood products company reputedly recommended warning hemophiliacs of link between its products and acquired immune deficiency syndrome. No warning was issued until early 1984.) See also *Ray v. Cutler Laboratories*, 744 F. Supp. 1124 (M.D. Fla. 1990).

91. It bears noting that the trend in the law is to encourage and protect whistleblowers. See, e.g., 5 U.S.C. § 2302(b)(8); 10 U.S.C. §§ 2409, 2409a; Cal. Lab. Code §§ 1102.5, 1103; Cal. Gov't Code § 19863.

92. See Lindell, *Biotech Firms Under the Microscope; Excess and Surplus Lines*, 91 BEST'S REVIEW—PROPERTY-CASUALTY INS. (Feb. 1991) ("Good manufacturing practices should go far beyond merely meeting FDA requirements for purity and consistency. They should include a meaningful commitment to responsible and legally correct actions in quality control, raw material supplier audits, product labelling, sales staff training and solicitation of post marketing surveillance.")

93. Not only will the firms command respect; they may benefit from assumption of the risk concepts and from inferences of no negligence.

94. Hilts, *Wave of Protests Developing on Profits From Aids Drug*, N.Y. Times, Sept. 16, 1989, at 1, col. 5.

Centoxin, a biotech drug used to treat septic infection, sells in the Netherlands and Great Britain at the equivalent of \$3,800 a dose, and is expected to be priced in the same range when it reaches the U.S. market.⁹⁵

In some cases the extraordinary price may reflect monopoly profits. Section 2 of the Sherman Antitrust Act prohibits monopolization.⁹⁶ The law against monopolization, however, is not a law against exorbitant profit-taking. It has been argued and judicially accepted that a monopoly price will simply draw new competition into the market, that in any event the courts are poor regulators of price, and that in the case of patents and intellectual property a higher than competitive price is a reward and inducement for innovation.⁹⁷

Policymakers in European nations generally disagree. In the European Economic Community, for example, a dominant firm that charges a price far in excess of value thereby abuses its dominant position.⁹⁸ This principal is heavily criticized by American scholars and business people as excessive and counter-productive market intervention.⁹⁹ However, if U.S. firms fail to check their own excesses regarding products critical to life and health, they are likely to invite extensions of section 2 of the Sherman Act or direct price regulations.

The high price of scarce drugs is of course not all profits. Centocor, the patentee of Centoxin, which was the first commercially-available, genetically-engineered human monoclonal antibody, reports that it spent at least \$250 million to develop the drug.¹⁰⁰ This extraordinary cost of development and production is a more intractable problem than excess profits. But the seller does not satisfy its social responsibility merely by proving that it spent \$250 million to develop a desperately needed and wanted drug and that it must regain its expenses by charging thousands of dollars per dose. The challenge of society is to devise procedures and guidelines for determining who will get what critical drug and how society will pay for it. The developer of the drug and its core of scientists and business-people are among the most knowledgeable, involved individuals who can and must commit themselves to serious participation in the search for solutions.

95. Winslow, *Dose of Reality: Costly Biotech Drugs Will Pose Hard Choices for U.S. Health Care*, Wall St. J., Nov. 5, 1991, at 1, col. 6.

96. 15 U.S.C. § 2 (1982).

97. *Berkey Photo, Inc. v. Eastman Kodak Co.*, 603 F.2d 263, 294 (2d Cir. 1979), cert. denied, 444 U.S. 1093 (1980).

98. See, e.g., *General Motors Continental N.V. v. Commission*, [1975] E.C.R. 1367; *Sirena v. Eda*, [1971] E.C.R. 69 (decided under Treaty of Rome Establishing the European Community, March 25, 1957, Art. 86.)

99. See, e.g., Kauper, *Whither Article 86? Observations on Excessive Prices and Refusals to Deal*, in *FORDHAM CORPORATE LAW INSTITUTE* (B. Hawk ed. 1989); *EEC/US COMPETITION AND TRADE LAW*, ch. 28 (1990).

100. See Winslow, *supra* note 95.

The market presence of extraordinarily costly biotech drugs will pose difficult questions in the 1990s.¹⁰¹ By the year 2000, we must be able to look back on the decade and say: The availability of these drugs, and the distribution of their costs of development, production, and accidents, was as fair and legitimate as possible.

VII. CONCLUSION

In the third-quarter of this century, a socially-conscious America developed a panoply of legal principles that expanded the potential liabilities of producers in numerous ways. Most of this law is sound and commendable. Much of it promotes important incentives to act with due care and places accountability on powerful companies. It concurrently evolved to protect the rights of individuals and to correct for injustices.

However, some decisions expanded the law beyond its policy goals, and undercut important societal needs. Legal principles that undermine incentives to invent and bring to market life-saving medical products are in this category. In the tradition of seeking legal change at the margin, where change makes an important difference, we suggest a limit to strict and quasi-strict product liability rules where they intrude into the most critical incentives to invent. In this spirit, we suggest a negligence-only rule for biotechnologically produced medical products.

101. *See id.*